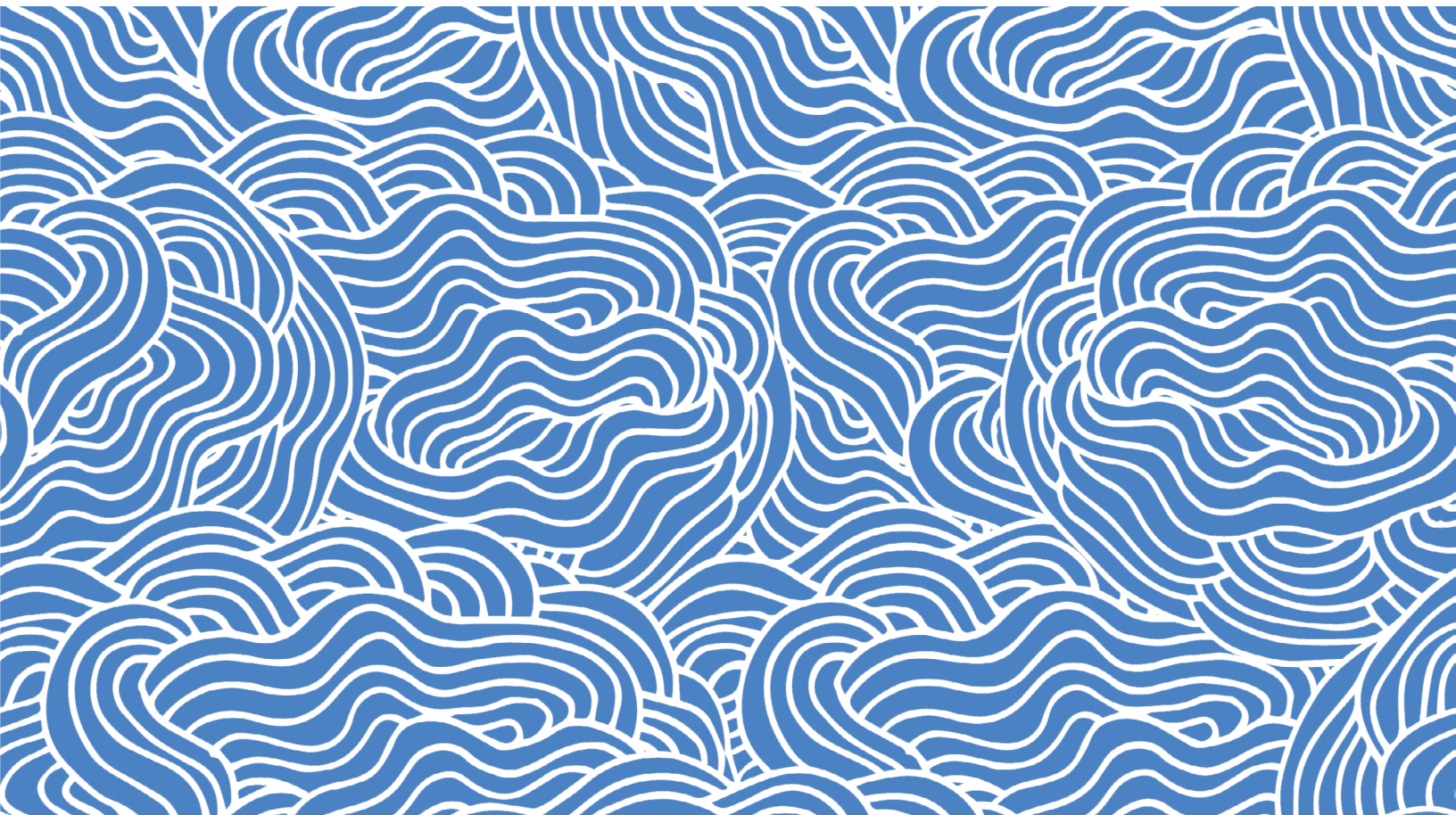




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Advancing Innovative Treatments for Mental Health Care

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INTRODUCTION

The mental health treatment gap is a public health issue requiring urgent investment and innovation. Mental health conditions are so pervasive in the United States that more than 50 percent of Americans will be diagnosed with a mental health condition at some point in their lifetime, with a continued rise predicted for the upcoming years.¹ However, more than one-half of adults with a mental health condition do not seek treatment.² Despite an increased focus on the unmet needs of people with mental health conditions, a significant treatment gap prevails, characterized by inadequate access to appropriate care and a lack of safe and effective therapies.³ Multidimensional factors and unprecedented societal pressures, stigma, joblessness, and economic hardship have collectively led to this public health issue and require an investment in equitable access to care and the adoption of healthy behaviors that address the root causes of the rapid rise in mental health conditions.⁴

Poor mental health impacts all aspects of life, including child development, social relationships, educational and career outcomes, social determinants of health, and overall well-being, as mental health conditions are often comorbid with other ailments. Investors in mental health treatments, health-care professionals, policymakers, and tele- and digital health service providers must invest in closing the mental health treatment gap to mitigate the impacts of mental health conditions.

Figure 1: Social Determinants of Health



Source: Milken Institute (2024), adapted from Healthy People 2030: <https://health.gov/healthypeople/priority-areas/social-determinants-health>

The Milken Institute's Public Health team leveraged its expertise through research, surveying, and interviewing esteemed experts and stakeholders from various sectors to report on treatment advancements and innovations for adults with depression, anxiety, post-traumatic stress disorder (PTSD),

and substance use disorder (SUD). These four conditions are among the most common in the US and, therefore, warrant greater innovation to improve prevention, management, and treatment.

From investments in new treatments to a greater emphasis on integrating a whole person health approach, detailed analysis of insights, policies, and treatments were informed through secondary research and expert interviews. Experts interviewed ranged from health-care providers, investors and start-ups in the mental health-care space, and public health leaders.⁵ This white paper provides an overview of key advancements in mental health treatment in the US and offers tangible actions for health-care providers, investors in mental health treatments, policymakers, and tele- and digital health service providers. Breaking down policy, stigma, access, and economic barriers is key to better supporting the mental and public health of our society.

WHERE WE STAND TODAY

Depression, anxiety, PTSD, and SUD have wide-ranging economic and social impacts in the US. **More than one in five American adults, about 57.8 million people, experienced “any mental illness,” defined as “a mental, behavioral, or emotional disorder,” in 2021.**⁶ In the same year, less than half (**47.2 percent**) of individuals who were diagnosed received treatment.⁷

These data highlight not only the mental health treatment gap but also the rapidly rising mental health crisis in the US. Rates of depression peaked in 2023, with 17.8 percent of Americans being treated for depression, a 4 percentage point increase from 2020. Overall, **29 percent of American adults report having ever been diagnosed with depression, an increase of 10 percentage points since 2015.**⁸ Anxiety, which is often comorbid with depression, impacts about **one-third of adults** at some point in their lives.⁹

About **6 percent of Americans will experience PTSD** at some point in their life, with higher lifetime prevalence rates among women (8 percent) and veterans (7 percent) because they are more likely to experience traumatic events, such as sexual assault or the trauma associated with military deployment.¹⁰ In 2021, **17.3 percent of American adults, or 44 million individuals, met the diagnostic criteria for SUD**, including both alcohol and drug use disorders.¹¹ These alarming statistics clearly illustrate a growing need for new treatments. It will be impossible to adapt to meet such rapidly increasing demand without fast-paced innovation.

For Brief Snapshots in History of Mental Health Policies and Treatments, please see page 20 in the Appendix.

Economic Impact of Mental Health Conditions

Individuals, communities, and society as a whole incur dramatic costs for mental health conditions, especially when left untreated. Poor mental health is associated with lower graduation rates and educational levels, and individuals with mental health conditions are less likely to be part of the workforce.¹² Furthermore, untreated mental health conditions are estimated to cost up to \$300 billion annually because of lost productivity and associated costs due to absenteeism, employee turnover, and increases in medical and disability expenses.¹³ A 2021 study showed that major depressive disorder (MDD) alone had an estimated economic burden of \$326 billion, with the direct cost of treating MDD accounting for only 11.2 percent of the overall economic burden.¹⁴



CHALLENGES OF INVESTMENTS AND FUNDING IN ADVANCING MENTAL HEALTH TREATMENTS

Despite the massive impact of the mental health treatment gap, innovation in mental health care has lagged far behind other medical fields. Although advances have revolutionized treatments for conditions such as cancer and heart disease, psychiatric practices have remained largely unchanged for decades. A root cause of this stagnation is profound funding and investment challenges unique to mental health research and product development; however, innovators are developing various digital and artificial intelligence (AI) markets for mental health.

The high monetary costs and risks of early-stage pharmaceutical research pose substantial barriers. Developing novel psychiatric medicines and treatments requires extensive research, with estimates of \$1.4 billion and more than a decade to bring a new drug to market.¹⁵ Failure rates are daunting—greater than 90 percent of candidate neuropsychiatric compounds fail in early trials.¹⁶ The average cost of Phase III trials for mental health indications is an estimated \$100 million.¹⁷

Given massive development costs, pharmaceutical companies are often reluctant to dedicate major investments without clear profitability projections. Mental health conditions receive disproportionately low industry research and development (R&D) funding. Although more than one-half the US population will be diagnosed with a mental health condition during their life, only about 5 percent of biopharma R&D budgets focus on new neuropsychiatric treatments.¹⁸

Academic researchers also face substantial obstacles to securing support. Public funding for mental health research through the National Institutes of Health (NIH) tends to provide conservative mental health research grants.¹⁹ Consequently, grant success rates have plummeted to only 15 percent for mental health applications, far below approval rates for other fields.²⁰ This scarcity funnels early discoveries into the “valley of death,” that is, the financing gap between discovery and clinical trial stages.²¹

Venture capital investment is similarly scarce for a variety of economic reasons, with most funds focused on medications in late-stage trials with faster payback. Furthermore, the few trials that secure early funding may still lack adequate capital for expensive late-stage trials. It is estimated that up to one-third of mental health discoveries fail to progress because of financing gaps between research phases.²²

Increasing funding across the development pipeline is critical to spur innovation in this underserved field. Recommended solutions include boosting government research budgets, incentivizing industry R&D through partnerships and reimbursement reform, expanding venture philanthropy, and establishing dedicated translational programs to bridge financing gaps from discovery through validation and commercialization. With improved funding and support, the mental health arena can realize its full potential for therapeutic breakthroughs that lessen the rising burden of mental illness.

REGULATORY HURDLES

The process of getting innovative psychiatric treatments and technologies to market is riddled with imposing regulatory barriers, including lengthy and expensive clinical trials that stifle progress. A key driver of long timelines is demonstrating unequivocal efficacy across adequate patient populations in well-controlled trials. Psychiatric studies often require thousands of patients to account for subjective endpoints, placebo effects, and disease heterogeneity. For example, the landmark clinical trials supporting Prozac's initial approval enrolled more than 3,000 patients.²³ The recent Spravato® (esketamine) trials enrolled nearly 2,000 patients.²⁴ The need for large sample sizes extends approval timelines.

The Food and Drug Administration (FDA) also mandates substantial safety assessments, given the risks of neurological and psychological side effects with psychoactive drugs. Stringent monitoring for adverse events, such as suicidal ideation, contributes to high Phase 3 failure rates.²⁵ Studies of therapies with modulating novel molecular targets face further regulatory uncertainty. In total, psychiatric drug development from discovery to approval lasts 14.2 years on average—longer than any other medical field.²⁶

Beyond drugs, regulatory precedence is lacking for emerging mental health digital and device technologies, such as brain stimulation and wearable biosensors that leverage AI and neurobiology. Uncertainties around evaluating efficacy and long-term safety with novel modalities can complicate approval pathways. The still nascent understanding of the molecular underpinnings of psychiatric diseases also stalls progress. Because evaluation of efficacy amid subjective psychiatric endpoints is challenging, pioneering approaches face additional regulatory burdens compared to established medical devices.

OTHER BARRIERS

Translating emerging biological insights into clinical innovations also demands collaboration across diverse scientific silos, presenting inherent challenges. Mental health innovation spans fields from neurobiology to pharmacology, genetics, computer science, engineering, and more. Limitations in shared data standards and infrastructures can hinder synergistic advances. Institutional barriers and research silos among academia, industry, and technology sectors further stifle open innovation and collaboration in unmet areas of need. Targeted efforts to foster communication and data sharing across stakeholders, including health-care providers, investors in mental health treatments, policymakers, and tele- and digital health service providers, are needed.

Overcoming these interlinked challenges will require efforts across multiple fronts—from anti-stigma advocacy, to basic research expansion to incentivize investment in early technologies and fostering multidisciplinary, open innovation and broad cross-sector collaboration. We can only deliver breakthrough solutions to long-standing mental health burdens through a supportive ecosystem that nurtures the full spectrum of innovation development.



POPULATION CONSIDERATIONS THAT IMPACT ACCESS TO MENTAL HEALTH TREATMENT

Alongside the great demand for mental health treatment, population considerations affect how and whether individuals access treatment. The US is built upon great geographic, cultural, and socioeconomic diversity. Different populations have various understandings and awareness of, sensitivity to, and access to care for mental health conditions. Population considerations and diversity in cultural perceptions affect how people experience and seek mental health care.

GEOGRAPHIC

With fewer mental health professionals (MHPs) living or practicing in rural communities, people who live in these areas would have to travel long distances to receive services. This geographic barrier and the time and money associated with traveling to see an MHP can be prohibitive even before calculating the cost of treatment itself. Furthermore, people who live in rural communities are more likely to face economic hardship and, therefore, less likely to be insured for mental health services.²⁷

Rural residents may also be more susceptible to the stigma of needing or receiving mental health care because they live in communities where having fewer choices of trained professionals can lead to a lack of faith in confidentiality.²⁸ A 2022 study of rural Americans found that 88 percent were either considering or in favor of telehealth, suggesting that these tele- and digital innovations would be a welcome intervention to expand access to care for rural communities.²⁹ Telehealth refers to remotely providing clinical services, whereas digital health represents the technologies individuals use, such as wearable devices and health information technology.

CULTURAL

Cultural norms, including culturally based stigma, may discourage people from talking about or seeking mental health care. Often, people may experience culturally based stigma through service barriers, including access and quality, fear of being a burden to one's family, lack of knowledge about mental health conditions, and specific cultural beliefs.³⁰ One way to combat culturally based stigma is to have more diverse representation in the mental health care profession. Many people do not seek mental health care because they cannot find a provider who understands their cultural background or speaks their language. Having an MHP who personally understands or shares one's cultural background may facilitate seeking help. It is key that the mental health profession be diversified, so all individuals can feel comfortable, seen, and encouraged to seek help.

Some cultural backgrounds face significant stigma around seeking mental health care. For example, individuals from Asian American and Pacific Islander (AAPI) backgrounds are 50 percent less likely than other ethnic groups to seek mental health services. Many within this community worry about the effect that talking about mental health could have on their ability to maintain employment and how they are perceived among their peers.³¹ The White House has suggested specific policies to support several stigmatized communities, including Asian Americans, to gain access to care.³²

The Importance of Cultural Competency and Sensitivity

By employing culturally sensitive approaches, MHPs better understand an individual's background and belief system as it relates to their race, ethnicity, sexual orientation, gender, or other important elements that make up someone's culture and/or identity.³³ Such approaches enable an MHP to develop cultural competency—the ability to first recognize and understand how one's culture influences one's relationship with a person, then understand and respond to a culture that differs from their own. In turn, individuals of diverse backgrounds will feel as though their culture is recognized, acknowledged, and respected.

GENERATIONAL DIVIDES

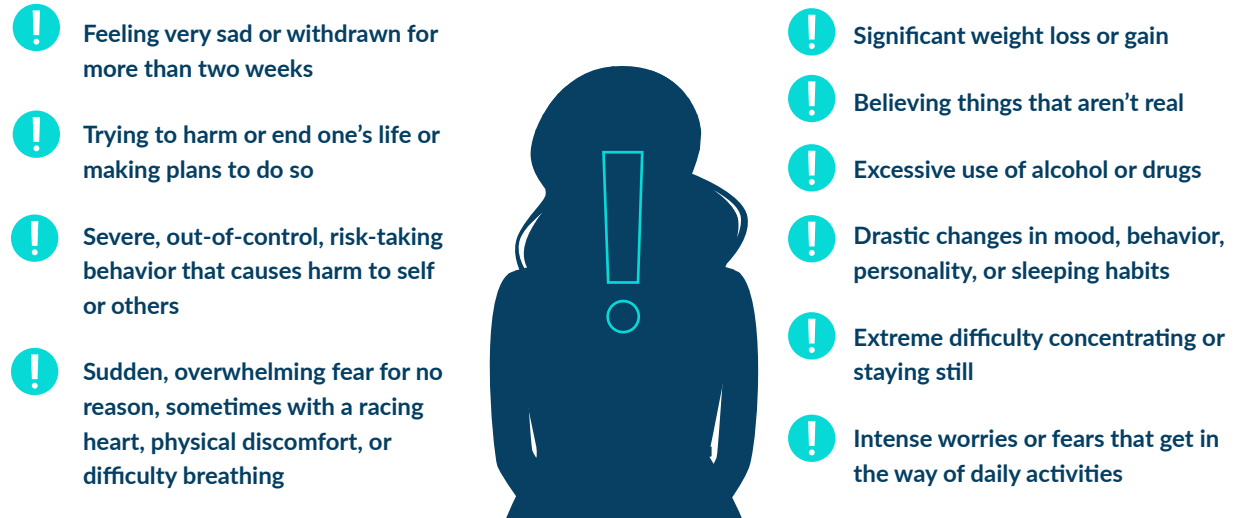
The prevalence of mental health conditions has risen significantly over the past few years, most notably since the COVID-19 pandemic. Young adults are more likely to have faced high levels of psychological distress since the pandemic, but many workplaces lack the infrastructure to meet the growing need for mental health treatment.³⁴ Since COVID-19, the US has experienced a shift in demands for mental health support and de-stigmatization, especially from Gen Z (people born between 1997 and 2012). Gen Z is championing more accessible and affordable mental health services by speaking out about mental health concerns, using de-stigmatizing language, and asking employers to provide expanded mental health benefits, which would benefit employees of all ages.

LACK OF MENTAL HEALTH AWARENESS

Individuals are often unaware that they have a mental health condition, do not know how to seek treatment, and lack access to treatment. Understanding warning signs for mental health conditions is key to early intervention. Early intervention is crucial because the longer it takes for someone to receive help, the more challenging their recovery can be. Delays in treatment can cause other serious consequences, such as limiting social and occupational opportunities and increasing the risk of depression and SUD.³⁵ Improving education and access, especially in rural areas and regions of lower socioeconomic status, can help encourage early intervention, limiting the long-term effects of an untreated mental health condition.

Figure 2: Common Warning Signs of Mental Health Conditions

Diagnosing mental health conditions can be challenging, as they are more difficult to test for than physical conditions. Common signs and/or symptoms may include:



- ! Feeling very sad or withdrawn for more than two weeks
- ! Trying to harm or end one's life or making plans to do so
- ! Severe, out-of-control, risk-taking behavior that causes harm to self or others
- ! Sudden, overwhelming fear for no reason, sometimes with a racing heart, physical discomfort, or difficulty breathing

- ! Significant weight loss or gain
- ! Believing things that aren't real
- ! Excessive use of alcohol or drugs
- ! Drastic changes in mood, behavior, personality, or sleeping habits
- ! Extreme difficulty concentrating or staying still
- ! Intense worries or fears that get in the way of daily activities

Source: Milken Institute (2024), adapted from the National Alliance on Mental Illness: <https://www.nami.org/NAMI/media/NAMI-Media/Infographics/NAMI-Warning-Signs-FINAL.pdf>

INNOVATIVE TREATMENTS

Innovative treatments, ranging from technological advances to novel medications, have the potential to close the mental health treatment gap. By offering a range of treatment options that appeal to people of various cultures and lifestyles, people can choose which treatment option works best for them, encouraging consistency of treatment and a path toward recovery.

EMBRACING TELE- AND DIGITAL HEALTH AND AI

During the pandemic, the use of tele- and digital health services rapidly increased. Although telehealth had been available for years, the pandemic marked the point when MHPs started to provide telehealth services at unparalleled scales and advance AI use for mental health diagnoses and treatment. As of September 2022, 88.1 percent of mental health facilities offered telehealth services compared with 39.4 percent of facilities in April 2019.³⁶ The accelerated adoption of telehealth redefined pre-existing barriers and has continued to encourage investment in this space following the pandemic.

This investment has been spurred, in part, because digital health technologies offer an increasing variety of apps and wearables that can help people track and manage their mental health conditions. For instance, some apps offer systems to track symptoms, habit formation or targeted behavior change, peer support, exercise and nutrition habits, and more. Oftentimes, these apps can be used with an MHP to set goals and visualize or track progress, including for people with SUD.³⁷

AI has the potential to improve mental health by increasing health-care access, personalized care, and early intervention. Opportunities in development are emerging in a range of areas: AI analysis of patient data for early detection, AI-driven algorithms to tailor and personalize treatment, virtual therapy with AI monitoring and support, and predictive analytics to forecast potential trends in mental health care.

The private sector has been fueling the growth of digital mental health treatment through a total \$29.1 billion investment in 2021.³⁸ Concurrently, the National Institute of Mental Health (NIMH) “has awarded over 400 grants for technology-enhanced mental health interventions.” According to NIMH, interventions include the following:³⁹

- technology for addressing a wide range of mental disorders, including depression and anxiety;
- interventions for cognitive issues, illness management, problematic behavior, and health communication;
- more accessible and engaging ways to deliver therapies or skill development (e.g., interactive formats or game-like approaches) and apps that work on any device; and
- active and passive mobile assessment and monitoring.

Although technological advances bring promise, traditional therapeutic methods remain invaluable because of their established efficacy. Cognitive-behavioral therapy (CBT), psychotherapy, and medication management have stood the test of time in addressing a wide spectrum of mental health conditions. The integration of traditional methods with innovative treatments provides a comprehensive toolkit that can

be tailored to individual needs. Research has demonstrated the equivalence within telemedicine delivery of cognitive processing therapy for PTSD, highlighting the potential of blending modern technology with evidence-based approaches.⁴⁰

ADVANTAGES OF TELEHEALTH IN INCREASING ACCESS TO MENTAL HEALTH SERVICES

Telehealth has significantly increased access to mental health services. Telehealth services allow people to see an MHP anywhere in their state from the comfort of their own space. This is especially true for individuals who live in rural communities where MHPs are scarce and might face a lengthy commute for an office visit. For people who work shift jobs and/or multiple jobs while managing a household, eliminating this travel allows them to spend more time at work or with family.

By not traveling to an MHP's office, people are more likely to keep their appointments and feel comfortable in their surroundings. Furthermore, the MHP can see the patient in their home; clues from their background can help the MHP better understand aspects of their patient's lives that they might not see in the office.⁴¹ In addition, families can be more involved in the treatment process when warranted.

CONSIDERATIONS AND CHALLENGES OF TELE- AND DIGITAL HEALTH AND AI

Broadband Access

Virtual and digital care is only useful if the individual has a sustainable broadband connection and a capable device, such as a smartphone or computer. Without a broadband connection (to which 14.5 million Americans lack access), people cannot connect via virtual methods, excluding them from the benefits of telehealth, digital health, and AI.⁴²

Privacy Challenges

Although individuals can log onto mental health care sessions from their homes or places of work, some individuals might experience privacy challenges, especially those with lower socioeconomic status. For instance, if someone lives in a home with multiple family members or attends the session while at work, they may feel as though they have insufficient privacy to express themselves or their needs. Furthermore, people may feel uncomfortable sharing their health data via digital health or AI platforms out of fear of data breaches or concerns about trust, identity, privacy, and security.⁴³

Quality of Care

Although telehealth increases access to mental health care, depending on an individual's condition, it is not equivalent to seeing a provider in person. Only 7 percent of all communication is conducted verbally; the rest is expressed nonverbally through the tonality of our voice and body language—38 percent and 55 percent, respectively.⁴⁴ AI technologies are being developed to help MHPs better understand what individuals are virtually communicating, but it is at the discretion of the professional to determine whether an individual should be seen in person or virtually, depending on their needs.

End of Public Health Emergency

Many policies established during the pandemic via the COVID-19 Public Health Emergency (PHE) have ended. The end of the PHE halted providers' ability to prescribe controlled substances through telehealth, depending on their credentials, geographic location, and state-specific flexibilities. Reverting to pre-PHE policies has limited access to mental health care that the pandemic policies had expanded, leaving many individuals without a provider or treatment. In addition to expanded capacity during the PHE, providers could be reimbursed for visits at the same rate, whether virtual or in person. Individuals who live in rural communities, those with more severe mental health conditions, and those with SUD continue to be among the most affected by this policy reversal.

INNOVATIVE THERAPIES

New therapies (including medicines and various novel treatments) generally take 9–15 years to enter the market because they need to move through discovery and development, preclinical research, clinical research, and FDA approval.⁴⁵ At times, the lack of innovative therapies can make individuals with mental health conditions and MHPs frustrated or pessimistic about prognosis and future outcomes. However, in recent years, as the mental health epidemic continues, the field has seen strides, including those listed below.


Future Landscape of Medications to Close the Gap

Many medications have entered the market over the past few years, holding potential promise for various mental health conditions ranging from depression and anxiety to SUD. One category of drug that is currently in development and in clinical trials is psychedelics. According to the FDA, classic psychedelics include psilocybin and lysergic acid diethylamide (LSD), as well as entactogens or empathogens such as methylenedioxymethamphetamine (MDMA).⁴⁶ Early clinical trials have indicated promising results for psychedelics. Early studies are ongoing to assess the benefit of on-site, clinician-directed therapy, namely “psychedelic-assisted therapy,” to help people with depression or PTSD.

Psychedelics induce a state of plasticity, which uncomplicates the rewiring of neuronal circuits. This provides the potential opportunity for psychedelic-assisted therapy to be clinically effective; however, further clinical research is required to confirm results.

With a rewiring of neuronal circuits, individuals, in turn, may embrace new social connections and new ways of thinking.⁴⁷ States that have approved the use of psilocybin (outside of the FDA's approval process) are taking steps to ensure that usage is on site in a licensed treatment center and that all aspects from manufacturing to delivery are regulated by state officials and an accompanying board of oversight.

The FDA has designated both MDMA and psilocybin as breakthrough therapies, which is a priority status given to promising drugs designed for an unmet need.⁴⁸ Data from early clinical trials show the potential for these therapies to offer hope to patients. Early research also shows that it is critical to combine these therapies with a comprehensive screening and risk assessment protocol to enable shared decision-making between patients and providers. This screening and risk assessment is important because psychedelics are known to produce hallucinogenic effects, and, as a result, there is a potential for abuse.⁴⁹ Consistent with therapeutic drug development, potential adverse reactions and family history must be carefully monitored and considered.



As research continues, there is tremendous opportunity for FDA-approved breakthroughs with novel and emerging treatments for mental health conditions. As the field progresses, newer versions of emerging psychedelic medications could be formulated to reduce the variability of patient responses and improve outcomes when carefully administered in supervised settings. Overall, patient safety balanced with patient access demonstrated through strong efficacy data in clinical trials remain the top priority within this developing domain.

With prudent screening, preparation, and monitoring procedures established, new therapies offer hope for treating mental health conditions that do not adequately respond to traditional interventions. Ongoing interdisciplinary research is critical to fully unlock the promise of these therapies while establishing ethical and responsible standards of care.

The medication pipeline for mental health conditions has substantially expanded during the past several years. These medications have the potential to increase treatment options and improve treatment for patients. The increased optionality in treatment could help providers identify a treatment regimen that best matches an individual's needs and improve the potential for treatments previously unavailable for patients. The approaches include:

- digital and AI-driven therapeutic solutions;
- virtual reality (including for anxiety through exposure therapy);
- tailored therapies and individualized medications that target specific neurotransmitters relevant to various mental health conditions;
- biomarker and genetics-based diagnostic tools for mental health disorders;
- innovative treatments addressing neuroinflammation and the influence of the gut microbiome on mental well-being;
- exploration of repurposed pharmaceuticals to address mental health concerns;
- AI-driven drug discovery methods for identifying novel compounds and predicting treatment outcomes in mental health; and
- development of interventions, such as psychedelic compounds, zuranolone, auvelity, VX-548, TPRV1, ALTO-100, oxytocin-targeting precision treatments, and genomic-based therapies, among other therapies.

Table 1: Medicines in Development for Mental Health Conditions

Mental Health Condition	Number of Medicines in Development (2023) ⁵⁰	Number of Medicines in Phase III Clinical Trials (2023)
Depression	55	8
Anxiety Disorders	35 (15 of which are indicated for PTSD)	7 (2 of which are indicated for PTSD)
PTSD	15	2
SUD	33	3
Totals	123	18

Source: PhRMA (2023), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/M-O/2023-MID_Mental-Illness_Drug-List_010323.pdf

How Innovative Treatments Can Close the Gap

Conventional mental health interventions often concentrate solely on symptom management. However, an intricate interconnection exists among mental, physical, emotional, and social aspects of well-being. Whole person care thrives on the collaborative care model that involves various interdisciplinary health-care professionals, including psychiatrists, psychologists, social workers, primary care physicians, mental health nurse practitioners, and occupational therapists.⁵¹ This multidisciplinary approach ensures that individuals receive a well-rounded and whole person treatment experience. By pooling their expertise and insights, health-care providers can offer comprehensive solutions that address physical, emotional, and social aspects of mental health. To view action steps to close the mental health treatment gap, please see page 22 in the Appendix.

By assessing the unique needs, preferences, and circumstances of each individual, MHPs can create treatment plans that weave together various interventions targeting the root causes of mental health concerns, transcending symptom management. The convergence of innovative treatments and traditional therapeutic methods offers a powerful approach to addressing the complex challenges of mental health conditions. For example, a treatment plan might include a combination of in-person therapy sessions, an exercise regimen, and a smartphone app for ongoing monitoring, feedback, and support. By marrying cutting-edge interventions with time-tested practices, MHPs can provide comprehensive, personalized, and effective care that caters to the diverse needs of individuals.

Figure 3: Whole Person Health



Source: Milken Institute (2023), adapted from the University of Michigan Model of Wellness: <https://hr.umich.edu/benefits-wellness/health-well-being/well-being-u-m>

ACTIONS TO ADDRESS THE BARRIERS TO MENTAL HEALTH TREATMENT

The US is at an inflection point for mental health care. Addressing key barriers, such as stigma, the provider shortage, challenges related to insurance coverage and reimbursement, and the need for more efficacious treatment options, is critical to improving the state of mental health in the US.

To see a full list of stakeholders and respective actions to address the mental health treatment gap, visit our Appendix on page 22-23.

ADDRESSING STIGMA

Insight: Stigma is a powerful barrier that can prevent people from seeking help, feeling comfortable sharing concerns with a health-care provider, feeling confident in their ability to adhere to a treatment plan, or functioning day to day. When stigma stifles the acknowledgment of warning signs and transparent conversations about mental health, the delay in seeking care can exacerbate symptoms, further social isolation, and increase self-stigma.⁵² Stigma can even limit treatment efficacy. Self-stigma, or internalized perceived societal stigma, can decrease treatment engagement and adherence, leading to poorer overall health outcomes.⁵³ Stigma is also associated with greater use of substances and lower confidence in one's ability to recover from SUD.⁵⁴

Furthermore, the structural stigma surrounding mental health conditions pervades both public opinion and professional communities, posing barriers to investment and innovation in many ways.⁵⁵ Stigma also complicates patient recruitment into clinical trials, which is particularly impactful in psychiatry given the requirements for large sample sizes (often thousands of patients) to demonstrate efficacy.⁵⁶ Because the impact of stigma on mental health is so pervasive, efforts to destigmatize mental health are crucial to closing the mental health treatment gap.

Action: Normalizing mental health conditions can increase awareness and encourage people to seek treatment. When speaking about mental health, it is important to be mindful of the language used to avoid further stigmatization. For example, using the phrase "mental illness" to refer to mental health conditions can be harmful because many people have negative associations with the word "illness." The language used to discuss mental health unconsciously impacts perceptions of mental health and perpetuates stigma, so the adoption of more neutral terminology can have a real, sustained impact.⁵⁷

State and federal policymakers can implement educational initiatives to raise awareness about mental health, normalize the conversation, and promote early intervention efforts. Education and awareness campaigns and the use of social media to normalize mental health can effectively combat stigma. Furthermore, *state and federal policymakers* can help mitigate the effect of media on mental health by strengthening online privacy and protection, addressing discriminatory algorithms, and conducting research on social media's impact on mental health to increase protective barriers. *Tele- and digital health services* can partner with workplaces to integrate and enhance programs that support employee mental health and cultivate workplace cultures that prioritize employee well-being.⁵⁸ Changing how mental health is talked about and

perceived has the potential to create a more welcoming, tolerant space that encourages people to seek help.

LACK OF EQUITABLE RESOURCES

Insight: Insurance and reimbursement challenges also impede access to mental health treatment. Without insurance, one hour of therapy can cost \$65 to \$250, which is cost-prohibitive for many Americans. Even insured individuals face challenges with coverage for mental health care, with average co-pays ranging between \$30 and \$50.⁵⁹ The majority of psychiatrists and other MHPs operate out of network because mental health conditions are not reimbursed to the same extent as physical health conditions. In 2017, for every \$1 insurance companies reimbursed primary care physicians in preferred provider organizations (PPOs), behavioral health professionals were reimbursed only 76 cents, evidence of reimbursement disparities between mental and physical health care.⁶⁰

Action: Creating parity in reimbursements may encourage more MHPs to operate under an insurance model, as opposed to a fee-for-service model, increasing access to MHPs. *Federal and state policies* could enforce and further strengthen health policy laws to ensure equitable coverage of medications and mental health services in insurance plans. Greater equity in coverage could be achieved, in part, by the Department of Health and Human Services further enforcing the Mental Health Parity and Addiction Equity Act of 2008 to ensure payment parity across providers. Furthermore, federal and state policies could expand Medicaid to increase access to mental health care and reduce financial barriers, enabling more people to access the mental health services they need. Increasing access to the best MHPs and dismantling financial barriers could help people with fewer resources access the mental health services they need.


LACK OF EQUITABLE ACCESS

Insight: Across the US, access to mental health care is not equitable. More than 150 million Americans live in federally designated MHP shortage areas.⁶¹ Nationally, 53.9 percent of US counties are without a single psychiatrist.⁶²

This shortage is especially acute and evident in rural regions, exacerbated by the disparity in reimbursement.⁶³ In 2022, for example, 60 percent of psychologists lacked the capacity to accept new patients, meaning that most people seeking help face waiting lists and lengthy delays to receive treatment if they can obtain care at all.⁶⁴ Simply too many are people in need and too few MHPs are available to treat them.

Action: Employing innovative strategies and technologies to increase early intervention of mental health conditions and access to MHPs is pivotal. All *health-care professionals*, including primary care physicians, should be equipped with mental health training to improve early identification and treatment of mental health conditions. These health-care professionals could then provide resources to combat mental health conditions before they start or when first noticed.

Moreover, incorporating *tele- and digital health services* as a part of workplace benefits could increase access to mental health support, especially for people in federally designated MHP shortage areas. Tele- and digital health will assist with early detection and enable people to track and maintain their



mental health more independently. Furthermore, using digitized guides and supports on tried-and-tested evidence-based treatments, such as CBT, can help lessen the overall demand for MHPs. Use of technology to develop coping skills, resiliency, and positive habits will lead to better mental health. Further examples of such technologies are outlined in the Innovative Treatments section.

BARRIERS TO ADVANCING INNOVATION

Insight: Financial and legal barriers impede innovations in mental health treatment. The unproven nature of pioneering treatment approaches can breed skepticism among investors and patients alike, limiting capital and trial recruitment. But this very skepticism propagates the funding gaps that prevent adequate clinical testing.


Mental health receives less research funding to advance treatment options than other health conditions. In 2022, NIH allocated \$7.6 billion for cancer research and \$6.5 billion for rare diseases compared to \$4 billion dollars for mental health.⁶⁵ Although philanthropic contributions and private-sector involvement have grown, the total investment remains comparatively limited. Greater than 80 percent of venture capital in biotech goes to late-stage assets, and unvalidated early-stage mental health technologies struggle for funding.⁶⁶

Furthermore, regulatory barriers, such as high approval standards set by agencies such as FDA, present major obstacles. Gaining FDA approval for a novel psychiatric medication requires extensive efficacy and safety testing in lengthy, expensive clinical trials.⁶⁷ These costs and risks deter investment in new neuropsychiatric drug development.

Moreover, regulatory precedence for emerging mental health digital and device technologies is lacking. Much remains unknown about the molecular underpinnings of psychiatric diseases; therefore, subjective measures are often used to gauge the effectiveness of non-pharmaceutical treatments. Decades of funding and policy disparities and the cumulative impact of stigma on public perception have manifested in system-wide barriers that have stifled development in the mental health field at a time of greater funding levels and more rapid innovation for other less stigmatized conditions.

Action: Increasing *mental health investments* from philanthropic, public, and private funders will propel mental health research, supporting the development of new treatments that are affordable and meet the nation's mental health needs. Creative financing solutions, such as venture philanthropy, can help catalyze emerging modalities. Furthermore, alleviating regulatory inefficiencies within *federal and state policies* through increased collaboration with agencies, such as FDA, will be key to expediting mental health innovations to patients. Policy reforms must balance safety and expedited access to novel therapies by advancing and supporting breakthrough mental health developments in a rapid cycle process review. The mental health field can fully leverage new scientific understanding and technologies to transform patient outcomes by overcoming regulatory hurdles.

Executive and legislative measures and campaigns will help to move the needle—imploping voters, policymakers, and organizations to understand the ramifications that prevention and recovery could have on society could help increase the dollars spent on mental health-care innovation. Having a stronger response to the US's mental health crisis would lead to a healthier nation while alleviating demand for other social programs.



Decades of stigma, lack of access and resources, and funding and policy challenges have manifested in system-wide barriers. These barriers have continued to stunt developments in the mental health field at a time of greater funding levels and more rapid innovation for other less stigmatized conditions. Increased spending on mental health innovation can be expected to advance the long-term economic and social benefits of prevention and recovery. Promising developments are on the horizon if stigma and other barriers to accessing them are dismantled.



CONCLUSION

By addressing the treatment gap, harnessing investment and innovation, emphasizing whole person health, and fostering collective efforts, stakeholders can collectively create a future in which mental health treatment is recognized, valued, supported, and accessible to all, leading to a healthier and more resilient society. To close the mental health treatment gap in the US, stakeholders should work to mitigate stigma, ensure reimbursement parity, increase access to mental health services, and encourage investments in innovation. Collaboration among investors in mental health treatments, health-care professionals, policymakers, and tele- and digital health services will be vital to ensuring that mental health treatment grows more accessible and affordable, improving public health for all.

APPENDIX

THE EVOLUTION OF MENTAL HEALTH POLICY AND TREATMENTS

Since the early 1900s, the US has made advances in mental health treatments, policies, and technologies. Mental health conditions have become better understood, and the approach to mental health care is more science-driven. From the asylums of the past to the contemporary era of evidence-based interventions, this evolution of policies and treatments illuminates the ongoing efforts to provide better care, reduce stigma, and enhance the lives of individuals grappling with mental health conditions. Although innovation has made strides, stigma and legal barriers often stifle advancement. The table below shows a snapshot, not a complete history, of mental health policy and treatments in the US.

Table 2: Snapshots in History of Mental Health Policies and Treatments

Year	Policies, Research, and Innovations
Early 1900s	The standard of mental health care included high-risk and often ineffective methods such as electroconvulsive therapy and lobotomies.
1946	The National Mental Health Act of 1946 established the National Institute of Mental Health, leading to numerous discoveries related to the causes, diagnosis, and treatment of mental health conditions. This commitment to improving the mental health of Americans was spurred by increasing concern for the well-being of World War II veterans who were demonstrating high rates of mental health conditions, including depression, anxiety, substance use disorder, and post-traumatic stress disorder.
1950s	The advent of antipsychotic medications and behavioral therapy became the basis for modern mental health treatments. The discovery of antipsychotic drugs initiated the deinstitutionalization movement. Individuals suffering from mental health conditions were released from state institutions, and most of those facilities were closed, in part because these therapies became more widely available and accepted as the standard of care. Unfortunately, funding was insufficient to establish clinics, community mental health centers, and other outpatient facilities needed to close the gap created by the deinstitutionalization movement as the state facilities that housed thousands of individuals were shuttered.
1962	The Food and Drug Administration designated lysergic acid diethylamide (LSD) as an experimental drug, which hindered research into its therapeutic potential.

1963	President John F. Kennedy signed the Community Mental Health Act, which provided federal funding for community mental health centers and research facilities.
1965	The creation of Medicaid furthered the momentum behind outpatient care because inpatient care in psychiatric hospitals would not be covered under the new program. However, not enough community mental health centers were built to meet the increased demand left by the closing of live-in institutions, creating a severe, prolonged gap in mental health care that continues to exist.
1971	LSD and other psychedelics were designated Schedule I drugs by the Controlled Substances Act, making them illegal for either medical or recreational use. ⁶⁸
1980s	Selective serotonin reuptake inhibitors (SSRIs), a class of medicine, were introduced to treat depression and anxiety and were viewed as safer alternatives to previous antipsychotic medications. ⁶⁹ The 1980s also saw the passage and repeal of the Mental Health Systems Act, which was intended to support and finance community mental health centers.
1990s	There was renewed interest and research in psychedelics as mental health treatments, but the field faced legal and stigma barriers that hindered its research, even today. However, the Schedule 1 classification made it difficult for researchers to study these substances and for companies to develop them as therapeutic products.
2008	The Mental Health Parity and Addiction Equity Act mandated insurance parity to ensure that requirements for mental health benefits were not more restrictive than those for medical and surgical benefits. ⁷⁰
2010	The Affordable Care Act increased health insurance coverage by expanding Medicaid eligibility and categorizing mental health services as an essential benefit.
2016	The 21st Century Cures Act accelerated medical product development while allocating \$1 billion in grants to states to support efforts related to the prevention and treatment of opioid use disorder. ⁷¹
2020s	A few states moved toward decriminalization of psychedelics, in part because of renewed interest in the medical uses of psychedelics and the movement to destigmatize SUD and treat addiction as a disease.

Source: Milken Institute (2024)

Table 3: Stakeholder Action Steps to Close the Mental Health Treatment Gap

This table represents the action steps stakeholders can take to support adults with anxiety, depression, PTSD, and SUD.

Stakeholder	Action	Goal
Health-Care Professionals	<ul style="list-style-type: none"> Equipping health-care professionals with mental health training to improve early identification and treatment of mental health conditions 	Enhancing their ability to provide effective care for mental health concerns
Tele- and Digital Health Services	<ul style="list-style-type: none"> Expanding telehealth services for mental health care, particularly in underserved areas, to enhance accessibility Partnering with employers to establish workplace mental health programs and invest in mental health technology solutions 	Increasing access to mental health services, especially in remote or underserved regions
Federal and State Policymakers	<ul style="list-style-type: none"> Enforcing and strengthening mental health parity laws to ensure equitable coverage of medications and mental health services in insurance plans Promoting public awareness and stigma reduction through executive and legislative measures and campaigns Advancing and supporting breakthrough mental health innovation through a rapid cycle process for review Establishing and funding national and regional mental health crisis hotlines, creating specialized mental health crisis response teams, and allocating funding for mental health services, research, and infrastructure development Strengthening online privacy and protection, addressing discriminatory algorithms, and conducting research on social media's impact on mental health Expanding Medicaid to increase access to mental health care and reduce financial barriers, with positive outcomes in terms of improved mental health Implementing educational initiatives in schools and communities to raise awareness and promote early intervention efforts 	Promoting equitable access to mental health services and reducing stigma associated with mental health conditions

Investors in Mental Health	<ul style="list-style-type: none"> Delivering research and development funding for innovative mental health medications and digital health services through the regulatory approval process, ensuring affordability, and conducting mental health impact assessments 	Advancing treatments, affordability, and assessing the economic impact of mental health programs
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Source: Milken Institute (2024)

Table 4: Whole Person Care Action Steps to Close the Mental Health Treatment Gap

Stakeholder	Action Steps to Close Mental Health Treatment Gap
Mental Health Professionals	<ul style="list-style-type: none"> Provide clinical assessments, diagnoses, and therapeutic interventions tailored to individual needs. Collaborate with other stakeholders to share insights and ensure a comprehensive understanding of the individual's mental health status. Design effective, evidence-based treatment plans encompassing psychological, emotional, and social dimensions.
Primary Care Physicians	<ul style="list-style-type: none"> Serve as the initial point of contact for individuals and recognize signs of mental distress. Refer people to specialized mental health services when needed. Address physical health concerns that may impact mental well-being, contributing to a holistic perspective.
Social Workers and Community Organizations	<ul style="list-style-type: none"> Identify social determinants of mental health, such as housing instability, financial difficulties, and social isolation. Collaborate with mental health providers to tailor interventions to address the broader social context of the individual. Promote a holistic approach to care by addressing social factors.
Policymakers and Advocacy Groups	<ul style="list-style-type: none"> Influence legislative and regulatory changes related to mental health. Allocate resources for mental health services, policies, and resources. Promote mental health awareness and destigmatization. Incorporate mental health policies and initiatives into the broader health-care framework.

Industry Treatment and Technology Innovators

- Conduct research and development to bring mental health products to market (i.e., digital and pharmaceutical products) through the regulatory approval process and subsequent post-authorization implementation.
- Develop and implement technological innovations, such as electronic health records and telemedicine platforms.
- Enable seamless communication and information sharing among stakeholders.
- Bridge gaps in communication to ensure informed and engaged care.

Patients and Families

- Participate actively in their mental health care, providing feedback and insights.
- Contribute to the development of effective treatment plans that respect their values, preferences, and cultural backgrounds.
- Provide valuable context to mental health providers and other stakeholders for a holistic understanding of their needs.

Source: Milken Institute (2024)

GLOSSARY

- **3,4-Methylenedioxymethamphetamine (MDMA):** A synthetic stimulant and hallucinogen that produces an energizing effect, distortions in time and perception, and enhanced enjoyment from sensory experiences.⁷²
- **Anxiety:** A mental health condition that produces fear, worry, and a constant feeling of being overwhelmed. It is characterized by excessive, persistent, and unrealistic worry about everyday things.⁷³
- **Behavioral Health:** Refers to mental health and substance use disorders, life stressors and crises, and stress-related physical symptoms.⁷⁴
- **Community:** Where people live, learn, work, and play.⁷⁵
- **Comorbid:** Existing simultaneously with and usually independently of another medical condition.⁷⁶
- **Deinstitutionalization:** The policy of moving people with severe mental health conditions out of large state institutions and then closing part or all of those institutions.⁷⁷
- **Depression:** A mental health condition characterized by at least two weeks of pervasive sadness, low energy, low self-esteem, and loss of interest or pleasure in normally enjoyable activities.⁷⁸
- **Downstream:** Refers to the treatment of symptoms or management of impacts of health conditions at the individual level as opposed to prevention or early intervention at a community level.⁷⁹
- **Electroconvulsive Therapy:** A medical treatment consisting of brief electrical stimulation of the brain via electrodes attached to the scalp at precise locations while the patient is under anesthesia.⁸⁰ It is used to treat schizophrenia, bipolar disorder, and severe, treatment-resistant depression.
- **Gen Z:** The generation born between 1997 and 2010.⁸¹
- **Health Equity:** Ensuring everyone has a fair and just opportunity to be as healthy as possible. This requires removing obstacles to health such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and health care.⁸²
- **Lobotomy:** A surgical procedure in which the nerve pathways in a lobe or lobes of the brain are severed from those in other areas. This can be done by removing part of the frontal lobe, surgically severing connections between the frontal lobe and thalamus, and injecting ethanol or drugs to harden the connective fibers between the frontal lobe and thalamus. It was formerly used to treat schizophrenia, bipolar disorder, and severe depression.⁸³
- **Lysergic Acid Diethylamide:** A psychedelic that produces changes in perception, mood, and thought.⁸⁴
- **Mental Health Condition:** Health conditions involving changes in emotion, thinking, or behavior

(or a combination of these).⁸⁵

- **Mental Health Professional:** Health-care practitioners or providers focused on mental health, inclusive of psychiatrists, psychologists, counselors, therapists, social workers, mental health nurse practitioners, and pharmacists.⁸⁶
- **Phase III:** The clinical trial phase in which the drug or treatment is given to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely.⁸⁷
- **Post-Traumatic Stress Disorder:** A psychiatric condition that may occur in people who have experienced or witnessed a traumatic event, series of events, or set of circumstances. It is characterized by intense, disturbing thoughts and feelings related to their experience, flashbacks or nightmares, feelings of sadness, fear, anger, and detachment, and strong negative reactions to stimuli such as touch or loud noises.⁸⁸
- **Psilocybin:** A hallucinogenic substance obtained from certain types of mushrooms.⁸⁹
- **Public Health:** Health of people and their communities.⁹⁰
- **Public Health Emergency:** A set of appropriate actions taken in response to a condition threatening adverse health consequences with the potential to overwhelm routine remedial capabilities of the community.⁹¹
- **Quality of Life:** An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.⁹²
- **Research and Development:** Creative and systematic work undertaken in order to increase the stock of knowledge—including knowledge of people, culture, and society—and to devise new applications using available knowledge.⁹³
- **Schedule I Drug:** A drug with no currently accepted medical use and a high potential for abuse.⁹⁴ The Controlled Substances Act of 1970 categorized all substances regulated under existing federal law into one of five schedules, including Schedule I.⁹⁵
- **Self-Stigma:** When perceived societal stigma is internalized. Self-stigma can result in loss of self-respect, decreased self-esteem, and loss of self-efficacy.⁹⁶
- **Social Determinants of Health:** Nonmedical factors that influence health outcomes. The conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces and systems include economic policies and systems, development agendas, social norms, social policies, racism, climate change, and political systems.⁹⁷
- **Social Programs:** Government programs, such as Medicaid, Supplemental Nutrition Assistance Program, Temporary Assistance for Needy Families, and Supplemental Security Income.
- **Space:** The physical environment in which an individual is comfortable and at ease, whether their home, workplace, or another location.⁹⁸

- **Stigma:** A societal process in which individuals within a society collectively apply stereotypes to an identifiable subgroup. Once a society also believes that negative connotations associated with stereotypes are applicable to all members of the subgroup, discrimination often results.⁹⁹
- **Structural Stigma:** The societal-level conditions, cultural norms, and institutional practices that constrain the opportunities, resources, and well-being for stigmatized populations.¹⁰⁰
- **Substance Use Disorder:** A condition in which there is uncontrolled use of a substance (alcohol and/or drugs) despite harmful consequences.¹⁰¹
- **Therapies:** A treatment that helps someone feel better, grow stronger, manage symptoms, or recover from a mental health condition. Examples include occupational, group, behavioral, and pharmaceutical therapies.¹⁰²
- **Treatment:** A method of addressing a health condition to mitigate or eliminate symptoms. Inclusive of pharmaceutical, behavioral, and whole person interventions.
- **Valley of Death:** The translational research phase of biomedical research. The phase between basic scientific research and clinical research, where promising discoveries often meet their demise. To cross the “Valley of Death,” several key requirements must be in place to move these discoveries into new treatments, diagnostics, and preventions.¹⁰³
- **Whole Person Health:** Whole person health looks at all the factors that affect well-being, including diet and exercise, stress, environment, genetics, behavior, and social networks.¹⁰⁴

ENDNOTES

1. “The National Mental Health Crisis,” American Psychological Association, January 1, 2021, <https://www.apa.org/monitor/2021/01/trends-national-crisis>.
2. Ronald C. Kessler, Matthias Angermeyer, James C. Anthony, et al., “Lifetime Prevalence and Age-of-Onset Distributions of Mental Disorders in the World Health Organization’s World Mental Health Survey Initiative,” *World Psychiatry* 6, no. 3 (October 2007): 169–176, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2174588/>.
3. Mental Health Has Bigger Challenges Than Stigma (Sapien Labs, 2021), <https://mentalstateoftheworld.report/wp-content/uploads/2021/05/Rapid-Report-2021-Help-Seeking.pdf>.
4. “Life Expectancy in the US Dropped for the Second Year in a Row in 2021,” Centers for Disease Control and Prevention, US Department of Health & Human Services, August 31, 2022, https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220831.htm.
5. To see a list of our experts, please look at page 28.
6. “Mental Illness,” National Institute of Mental Health, March 2023, <https://www.nimh.nih.gov/health/statistics/mental-illness>.
7. “Mental Illness,” National Institute of Mental Health.
8. Dan Witters, “US Depression Rates Reach New Highs,” Gallup, May 17, 2023, <https://news.gallup.com/poll/505745/depression-rates-reach-new-highs.aspx>.
9. “Any Anxiety Disorder,” National Institute of Mental Health, accessed August 24, 2023, <https://www.nimh.nih.gov/health/statistics/any-anxiety-disorder>.
10. “How Common Is PTSD in Adults?” US Department of Veterans Affairs, accessed January 9, 2024, https://www.ptsd.va.gov/understand/common/common_adults.asp#:~:text=About%205%20out%20of%20every,some%20point%20in%20their%20life.
11. 2021 National Survey of Drug Use and Health (NSDUH) (Substance Abuse and Mental Health Services Administration, US Department of Health and Human Services, January 4, 2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt39441/NSDUHDetailedTabs2021/NSDUHDetailedTabs2021/NSDUHDetTabsSect5pe2021.htm>.
12. Reducing the Economic Burden of Unmet Mental Health Needs (White House, 2022), <https://www.whitehouse.gov/cea/written-materials/2022/05/31/reducing-the-economic-burden-of-unmet-mental-health-needs/>.
13. Mental Health Research & Innovation (National Alliance on Mental Illness, 2017), https://www.nami.org/getattachment/Get-Involved/NAMI-National-Convention/Convention-Program-Schedule/Hill-Day-2017/FINAL-Hill-Day-17_Research-and-Innovation-Leave-Behind.pdf.

14. Paul E. Greenberg, Andree-Anne Fournier, Tammy Sisitsky, Mark Simes, Richard Berman, Sarah H. Koenigsberg, and Ronald C. Kessler, “The Economic Burden of Adults with Major Depressive Disorder in the United States (2010 and 2018),” *Pharmacoeconomics* 39, no. 6 (2021): 653–665, <https://link.springer.com/article/10.1007/s40273-021-01019-4>.
15. Katherine W. Scangos, Matthew W. State, Andrew H. Miller, Justin T. Baker, and Leanne M. Williams, “New and Emerging Approaches to Treat Psychiatric Disorders,” *Nature Medicine* 29, no. 2 (2023): 317–333, <https://www.nature.com/articles/s41591-022-02197-0>.
16. Duxin Sun, Wei Gao, Hongxiang Hu, and Simon Zhou, “Why 90% of Clinical Drug Development Fails and How to Improve It,” *Acta Pharmaceutica Sinica B* 12, no. 7 (2022): 3049–3062, <https://www.sciencedirect.com/science/article/pii/S2211383522000521>.
17. Linda Martin, Melissa Hutchens, Conrad Hawkins, and Alaina Radnov, “How Much Do Clinical Trials Cost,” *Nature Reviews Drug Discovery* 16, no. 6 (2017): 381–382, <https://www.nature.com/articles/nrd.2017.70>.
18. “The National Mental Health Crisis,” American Psychological Association.; Daniel Arias, Shekhar Saxena, and Stéphane Verguet, “Quantifying the Global Burden of Mental Disorders and Their Economic Value,” *EClinicalMedicine* 54 (2022), [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(22\)00405-9/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(22)00405-9/fulltext).
19. “New NIMH Strategic Plan Paves the Way for Advances in Mental Health Research,” National Institute of Mental Health, May 20, 2020, <https://www.nimh.nih.gov/news/science-news/2020/new-nimh-strategic-plan-paves-the-way-for-advances-in-mental-health-research>.
20. “Budget,” National Institutes of Health, October 24, 2023, <https://www.nih.gov/ABOUT-NIH/WHAT-WE-DO/BUDGET>.
21. Attila A. Seyhan, “Lost in Translation: The Valley of Death across Preclinical and Clinical Divide—Identification of Problems and Overcoming Obstacles,” *Translational Medicine Communications* 4, no. 1 (2019): 1–19, <https://link.springer.com/article/10.1186/s41231-019-0050-7>.
22. Ole A. Andreassen, Guy F.L. Hindley, Oleksandr Frei, and Olav B. Smeland, “New Insights from the Last Decade of Research in Psychiatric Genetics: Discoveries, Challenges and Clinical implications,” *World Psychiatry* 22, no. 1 (2023): 4–24, <https://onlinelibrary.wiley.com/doi/full/10.1002/wps.21034>.
23. Paul Benfield, Rennie C. Heel, and Susan P. Lewis, “Fluoxetine: A Review of Its Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Efficacy in Depressive Illness,” *Drugs* 32 (1986): 481–508, <https://link.springer.com/article/10.2165/00003495-198632060-00002>.
24. Andreas Reif, Istvan Bitter, Jozefien Buyze, Kerstin Cebulla, Richard Frey, Dong-Jing Fu, Tetsuro Ito, et al., “Esketamine Nasal Spray Versus Quetiapine for Treatment-Resistant Depression,” *New England Journal of Medicine* 389, no. 14 (2023): 1298–1309, <https://www.nejm.org/doi/full/10.1056/NEJMoa2304145>.

25. Katye Stevens, Vivetha Thambinathan, Elisa Hollenberg, Fiona Inglis, Andrew Johnson, Andrea Levinson, Soha Salman, et al., “Core Components and Strategies for Suicide and Risk Management Protocols in Mental Health Research: A Scoping Review,” *BMC Psychiatry* 21, no. 1 (2021): 1–14, <https://bmcp psychiatry.biomedcentral.com/articles/10.1186/s12888-020-03005-0>.
26. Michael Dickson and Jean Paul Gagnon, “Key Factors in the Rising Cost of New Drug Discovery and Development,” *Nature Reviews Drug Discovery* 3, no. 5 (2004): 417–429, <https://www.nature.com/articles/nrd1382>.
27. Steven S. Coughlin, Catherine Clary, J. Aaron Johnson, Adam Berman, Vahe Heboyan, Teal Benevides, Justin Moore, and Varghese George, “Continuing Challenges in Rural Health in the United States,” *Journal of Environment and Health Sciences* 5, no. 2 (2019): 90, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7043306/>.
28. “Rural Mental Health Overview,” Rural Health Information Hub, November 30, 2023, <https://www.ruralhealthinfo.org/topics/mental-health>.
29. Shreya Kolluri, Thor S. Stead, Rohan K. Mangal, R. Lane Coffee Jr, Jonathan Littell, and Latha Ganti, “Telehealth in Response to the Rural Health Disparity,” *Health Psychology Research* 10, no. 3 (2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9392842/>.
30. Supriya Misra, Valerie W. Jackson, Jeanette Chong, Karen Choe, Charisse Tay, Jazmine Wong, and Lawrence H. Yang, “Systematic Review of Cultural Aspects of Stigma and Mental Illness among Racial and Ethnic Minority Groups in the United States: Implications for Interventions,” *American Journal of Community Psychology* 68, no. 3-4 (2021): 486–512, <https://onlinelibrary.wiley.com/doi/abs/10.1002/ajcp.12516>.
31. Jocelyn Apodaca Schlossberg, “Confronting Mental Health Barriers in the Asian American and Pacific Islander Community,” *UCLA Health*, May 9, 2023, <https://www.uclahealth.org/news/confronting-mental-health-barriers-asian-american-and-2#:~:text=Overall%2C%20Asian%20Americans%20are%2050,or%20depression%20is%20rarely%20encouraged>.
32. “FACT SHEET: Biden--Harris Administration Takes Action to Promote Access to Behavioral Health Care for Asian American, Native Hawaiian, and Pacific Islander Communities,” The White House, July 26, 2023, <https://www.whitehouse.gov/briefing-room/statements-releases/2023/07/26/fact-sheet-biden-harris-administration-takes-action-to-promote-access-to-behavioral-health-care-for-asian-american-native-hawaiian-and-pacific-islander-communities/>.
33. “Culturally Sensitive Therapy,” *Psychology Today*, September 19, 2022, <https://www.psychologytoday.com/us/therapy-types/culturally-sensitive-therapy>.
34. John Gramlich, “Mental Health and the Pandemic: What US Surveys Have Found,” Pew Research Center, March 2, 2023, <https://www.pewresearch.org/short-reads/2023/03/02/mental-health-and-the-pandemic-what-u-s-surveys-have-found/>.

35. “The Importance of Early Intervention for People Facing Mental Health Challenges,” Mental Health First Aid USA, June 21, 2021, <https://www.mentalhealthfirstaid.org/2021/06/the-importance-of-early-intervention-for-people-facing-mental-health-challenges/>.
36. Ryan K. McBain, Megan S. Schuler, Nabeel Qureshi, Samantha Matthews, Aaron Kofner, Joshua Breslau, and Jonathan H. Cantor, “Expansion of Telehealth Availability for Mental Health Care after State-Level Policy Changes from 2019 to 2022,” JAMA Network Open 6, no. 6 (2023): e2318045-e2318045, <https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2805968>.
37. “Digital Mental Health,” Psychiatry.org, accessed October 11, 2023, <https://www.psychiatry.org/psychiatrists/practice/digital-mental-health>.
38. Adriana Krasniansky, Bill Evans, and Megan Zweig, “2021 Year-End Digital Health Funding: Seismic Shifts beneath the Surface,” Rock Health, January 10, 2022, <https://rockhealth.com/insights/2021-year-end-digital-health-funding-seismic-shifts-beneath-the-surface/>.
39. “Technology and the Future of Mental Health Treatment,” National Institute of Mental Health, June 2023, <https://www.nimh.nih.gov/health/topics/technology-and-the-future-of-mental-health-treatment>.
40. Leslie A. Morland, Margaret-Anne Mackintosh, Craig S. Rosen, Emy Willis, Patricia Resick, Kathleen Chard, and B. Christopher Frueh, “Telemedicine versus In-Person Delivery of Cognitive Processing Therapy for Women with Posttraumatic Stress Disorder: A Randomized Noninferiority Trial,” Depression and Anxiety 32, no. 11 (2015): 811–820, <https://onlinelibrary.wiley.com/doi/abs/10.1002/da.22397>.
41. For the purpose of this white paper, the term “patient” is used to address the person seeking mental health treatment. However, many MPHs (those without medical training) refer to these people as “clients.”
42. United States Federal Communications Commission, Fourteenth Broadband Deployment Report. FCC 21-18 (Federal Communications Commission, 2021), <https://docs.fcc.gov/public/attachments/FCC-21-18A1.pdf>.
43. Richard Brown, “Why People Don’t Share Their Health Data,” Psychology Today, May 15, 2022, <https://www.psychologytoday.com/us/blog/understanding-health-behaviors/202205/why-people-don-t-share-their-health-data>.
44. Jon Michail, “Strong Nonverbal Skills Matter Now More Than Ever in This ‘New Normal,’” Forbes, August 24, 2020, <https://www.forbes.com/sites/forbescoachescouncil/2020/08/24/strong-nonverbal-skills-matter-now-more-than-ever-in-this-new-normal/?sh=33296b345c61>.
45. Peggy L. O’Brien, Cindy Parks Thomas, Dominic Hodgkin, Katharine R. Levit, and Tami L. Mark, “The Diminished Pipeline for Medications to Treat Mental Health and Substance Use Disorders,” Psychiatric Services 65, no. 12 (2014): 1433–1438, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4788407/>.

46. “FDA Issues First Draft Guidance on Clinical Trials with Psychedelic Drugs,” US Food and Drug Administration, June 23, 2023, <https://www.fda.gov/news-events/press-announcements/fda-issues-first-draft-guidance-clinical-trials-psychedelic-drugs>.
47. Emma Yasinski, “Why Psychedelic Drugs May Become a Key Treatment for PTSD and Depression,” Smithsonian Magazine, May 3, 2022, <https://www.smithsonianmag.com/science-nature/why-psychedelic-drugs-may-become-a-key-treatment-for-ptsd-and-depression-180979983/>.
48. Emma Yasinski, Why Psychedelic Drugs May Become a Key Treatment for PTSD and Depression.”
49. Pantelis Leptourgos, Martin Fortier-Davy, Robin Carhart-Harris, Philip R. Corlett, David Dupuis, Adam L. Halberstadt, Michael Kometer, et al., “Hallucinations under Psychedelics and in the Schizophrenia Spectrum: An Interdisciplinary and Multiscale Comparison,” Schizophrenia Bulletin 46, no. 6 (2020): 1396–1408, [doi: 10.1093/schbul/sbaa117](https://doi.org/10.1093/schbul/sbaa117).
50. 2023 Medicines in Development—Mental Illness (PhRMA, 2023), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/M-O/2023-MID_Mental-Illness_Drug-List_010323.pdf.
51. Christopher Reist, Incia Petiwala, Jennifer Latimer, Sarah Borish Raffaelli, Maurice Chiang, Daniel Eisenberg, and Scott Campbell, “Collaborative Mental Health Care: A Narrative Review,” Medicine 101, no. 52 (2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9803502/>.
52. “The Importance of Early Intervention for People Facing Mental Health Challenges,” Mental Health First Aid USA.
53. Kathleen A. Crapanzano, Rebecca Hammarlund, Bilal Ahmad, Natalie Hunsinger, and Rumneet Kullar, “The Association Between Perceived Stigma and Substance Use Disorder Treatment Outcomes: A Review,” Substance Abuse and Rehabilitation (2018): 1–12, <https://www.tandfonline.com/doi/full/10.2147/SAR.S183252>.
54. Kathleen A. Crapanzano, Rebecca Hammarlund, Bilal Ahmad, Natalie Hunsinger, and Rumneet Kullar, “The Association Between Perceived Stigma and Substance Use Disorder Treatment Outcomes: A Review.”
55. B. A. Pescosolido, et al, “Rethinking Theoretical Approaches to Stigma: A Framework Integrating Normative Influences on Stigma (FINIS),” Social Science & Medicine, 2008, <https://www.sciencedirect.com/science/article/abs/pii/S0277953608001512>,
56. Niina Laaksonen, Mia Bengtström, Anna Axelin, Juuso Blomster, Mika Scheinin, and Risto Huupponen, “Success and Failure Factors of Patient Recruitment for Industry-Sponsored Clinical Trials and the Role of the Electronic Health Records—A Qualitative Interview Study in the Nordic Countries,” Trials 23, no. 1 (2022): 385, <https://link.springer.com/article/10.1186/s13063-022-06144-9>.
57. Janet Zwick, Hannah Appleseth, and Stephan Arndt. “Stigma: How It Affects the Substance Use Disorder Patient,” Substance Abuse Treatment, Prevention, and Policy 15 (2020): 1–4, <https://link.springer.com/article/10.1186/s13011-020-00288-0>.

58. "Mental Health," Milken Institute, accessed October 10, 2023, <https://milkeninstitute.org/centers/center-for-public-health/mental-health>.
59. Megan Leonhardt, "What You Need to Know About the Cost and Accessibility of Mental Health Care in America," CNBC, May 10, 2021, <https://www.cnbc.com/2021/05/10/cost-and-accessibility-of-mental-health-care-in-america.html>.; Bill Fay, "Health Insurance Premiums, Deductibles, Copays and Coinsurance," Debt.org, November 4, 2020, <https://www.debt.org/medical/health-insurance-premiums/>.
60. Stoddard Davenport, Travis Gray, Stephen P. Melek, Addiction and Mental Health Vs. Physical Health: Widening Disparities in Network Use and Provider Reimbursement (Milliman, November 20, 2019), <https://www.milliman.com/en/insight/addiction-and-mental-health-vs-physical-health-widening-disparities-in-network-use-and-p>.
61. MHPs include psychiatrists, psychologists, counselors, therapists, social workers, mental health nurse practitioners, and pharmacists focused on mental health.; "Mental Health Care Health Professional Shortage Areas (HPSAs)," KFF, November 1, 2023, <https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/>.
62. Stacy Weiner, "A Growing Psychiatrist Shortage and an Enormous Demand for Mental Health Services," AAMC, August 9, 2022, <https://www.aamc.org/news/growing-psychiatrist-shortage-enormous-demand-mental-health-services>.
63. University of Michigan Behavioral Health Workforce Research Center, Estimating the Distribution of the US Psychiatric Subspecialist Workforce (UMSPH, 2018), https://behavioralhealthworkforce.org/wp-content/uploads/2019/02/Y3-FA2-P2-Psych-Sub_Full-Report-FINAL2.19.2019.pdf.
64. "Psychologists Struggle to Meet Demand amid Mental Health Crisis," American Psychological Association, 2022.
65. "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," National Institutes of Health, March 31, 2023, <https://report.nih.gov/funding/categorical-spending#/>.
66. Melanie Senior, "Pharma Backs Off Biotech Acquisitions," Nature Biotechnology 40 (2022): 1546–1550, <https://www.nature.com/articles/s41587-022-01529-2>.
67. "Drug Development & Approval Process," US Food and Drug Administration, August 8, 2022, <https://www.fda.gov/drugs/development-approval-process-drugs>.
68. "The Controlled Substances Act," Drug Enforcement Administration, accessed September 12, 2023, <https://www.dea.gov/drug-information/csa>.
69. Bryan Bruno, "The History of Antidepressants," Mid City TMS, November 17, 2021, <https://www.midcitytms.com/the-history-of-antidepressants/>.

70. “Departments of Labor, Health and Human Services, Treasury Announce Proposed Rules to Strengthen Mental Health Parity and Addiction Equity Act,” US Department of Health and Human Services, July 25, 2023, <https://www.hhs.gov/about/news/2023/07/25/departments-labor-health-human-services-treasury-announce-proposed-rules-strengthen-mental-health-parity-addiction-equity-act.html#:~:text=Enacted%20in%202008%2C%20the%20Mental,for%20medical%20and%20surgical%20conditions.>
71. “21st Century Cures Act,” US Food and Drug Administration, January 31, 2020, <https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act.>
72. “What Is MDMA?” National Institute on Drug Abuse, September 2017, <https://nida.nih.gov/publications/research-reports/mdma-ecstasy-abuse/what-mdma.>
73. S. Munir and V. Takov, “Generalized Anxiety Disorder (GAD) [updated January 2023],” Statpearls [internet]. Treasure Island (fl): Statpearls Publishing (October 17, 2022). [https://pubmed.ncbi.nlm.nih.gov/28722900/.](https://pubmed.ncbi.nlm.nih.gov/28722900/)
74. “What Is Behavioral Health?” American Medical Association, August 22, 2022, <https://www.ama-assn.org/delivering-care/public-health/what-behavioral-health.>
75. “Supply Chain Control Towers: Providing End-to-End Visibility,” SAP Insights (blog), accessed February 3, 2023, <https://www.sap.com/insights/supply-chain-control-tower.html#:~:text=What%20is%20a%20supply%20chain,to%20proactively%20manage%20supply%20chains.>
76. “Comorbid,” Merriam-Webster, accessed October 12, 2023, <https://www.merriam-webster.com/dictionary/comorbid.>
77. Edwin Valdiserri, “Deinstitutionalization—Special Reports | The New Asylums | FRONTLINE,” PBS, May 10, 2005, <https://www.pbs.org/wgbh/pages/frontline/shows/asylums/special/excerpt.html.>
78. “What Is Depression?” American Psychiatric Association, accessed September 7, 2023, <https://www.psychiatry.org/patients-families/depression/what-is-depression.>
79. “Examples in Action,” Moving Health Care Upstream, accessed January 9, 2024, <https://www.movinghealthcareupstream.org/examples-in-action-2/#:~:text=Midstream%20efforts%20seek%20to%20create,impact%20by%20providing%20clinical%20care.>
80. “What Is Electroconvulsive Therapy (ECT)?,” American Psychiatric Association, January 2023, <https://www.psychiatry.org/patients-families/ect.>
81. Michael Dimock, “Defining Generations: Where Millennials End and Generation Z Begins,” Pew Research Center, January 17, 2019, [https://www.pewresearch.org/short-reads/2019/01/17/where-millennials-end-and-generation-z-begins/.](https://www.pewresearch.org/short-reads/2019/01/17/where-millennials-end-and-generation-z-begins/)
82. What Is Health Equity? And What Difference Does a Definition Make? (Robert Wood Johnson Foundation, 2017), <https://www.rwjf.org/content/dam/farm/reports/reports/2017/rwjf437343#:~:text=Health%20equity%20is%20the%20ethical,affect%20marginalized%20or%20excluded%20groups.>

83. "Lobotomy," Britannica, accessed September 7, 2023, <https://www.britannica.com/science/lobotomy>.
84. "LSD," Alcohol and Drug Foundation, November 23, 2023, <https://adf.org.au/drug-facts/lsd/>.
85. "What Is Mental Illness?" American Psychiatric Association, accessed September 7, 2023, <https://www.psychiatry.org/patients-families/what-is-mental-illness>.
86. "Types of Mental Health Professionals," National Alliance on Mental Illness, April 2020, <https://www.nami.org/About-Mental-Illness/Treatments/Types-of-Mental-Health-Professionals>.
87. "NIH Clinical Research Trials and You: The Basics," National Institutes of Health, October 3, 2022, <https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics>.
88. "What Is Posttraumatic Stress Disorder (PTSD)?" American Psychiatric Association, accessed September 7, 2023, <https://www.psychiatry.org/patients-families/ptsd/what-is-ptsd>.
89. "Psilocybin Fast Facts," National Drug Intelligence Center, January 1, 2006, <https://www.justice.gov/archive/ndic/pubs6/6038/index.htm#:~:text=Psilocybin%20is%20a%20hallucinogenic%20substance,of%20psilocyn%2C%20another%20hallucinogenic%20substance>.
90. "What Is Public Health?" American Public Health Association, accessed February 3, 2023, <https://www.apha.org/what-is-public-health>.
91. "A Public Health Emergency Declaration," Administration for Strategic Preparedness and Response, accessed November 22, 2023, <https://aspr.hhs.gov/legal/PHE/Pages/Public-Health-Emergency-Declaration.aspx#:~:text=The%20Secretary%20of%20the%20Department,of%20infectious%20disease%20or%20bioterrorist>; Christopher Nelson, Nicole Lurie, Jeffrey Wasserman, and Sarah Zakowski, "Conceptualizing and Defining Public Health Emergency Preparedness," American Journal of Public Health 97, no. Supplement_1 (2007): S9–S11, <https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2007.114496>.
92. "WHOQOL: Measuring Quality of Life," World Health Organization, accessed October 12, 2023, <https://www.who.int/tools/whoqol>.
93. Circular No. A-11 Preparation, Submission, and Execution of the Budget (Executive Office of the President, Office of Management and Budget, August 2023), <https://www.whitehouse.gov/wp-content/uploads/2018/06/a11.pdf>.
94. "Drug Scheduling," Drug Enforcement Administration, accessed September 12, 2023, <https://www.dea.gov/drug-information/drug-scheduling#:~:text=Schedule%20I%20drugs%2C%20substances%2C%20or,%2C%20methaqualone%2C%20and%20peyote>.
95. "The Controlled Substances Act," Drug Enforcement Administration, accessed September 12, 2023, <https://www.dea.gov/drug-information/csa>.
96. Kathleen A. Crapanzano, Rebecca Hammarlund, Bilal Ahmad, Natalie Hunsinger, and Rumneet Kullar, "The Association between Perceived Stigma and Substance Use Disorder Treatment Outcomes: A Review."

97. "Social Determinants of Health at CDC," Centers for Disease Control and Prevention, December 8, 2022, <https://www.cdc.gov/about/sdoh/index.html>.
98. In reference to "space" in Advantages of Telehealth in Increasing Access to Mental Health Services section.
99. Kathleen A. Crapanzano, Rebecca Hammarlund, Bilal Ahmad, Natalie Hunsinger, and Rumneet Kullar, "The Association between Perceived Stigma and Substance Use Disorder Treatment Outcomes: A Review."
100. Mark L. Hatzenbuehler and Bruce G. Link, "Introduction to the Special Issue on Structural Stigma and Health," *Social Science & Medicine* 103 (2014): 1–6, <https://www.sciencedirect.com/science/article/abs/pii/S0277953613007090>.
101. "What Is a Substance Use Disorder?" American Psychiatric Association, accessed September 7, 2023, <https://www.psychiatry.org/patients-families/addiction-substance-use-disorders/what-is-a-substance-use-disorder>.
102. "Therapy," Cambridge Dictionary, accessed October 12, 2023, <https://dictionary.cambridge.org/dictionary/english/therapy>.
103. Attila A. Seyhan, "Lost in Translation: The Valley of Death Across Preclinical and Clinical Divide—Identification of Problems and Overcoming Obstacles." <https://link.springer.com/article/10.1186/s41231-019-0050-7/>.
104. "Whole Person Health," NIH News in Health, June 2022, <https://newsinhealth.nih.gov/2022/06/whole-person-health#:~:text=Whole%20person%20health%20looks%20at,lead%20you%20away%20from%20it>.

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