National Council Medical Director Institute









Medication Matters

Causes and Solutions to Medication Non-Adherence

NATIONAL
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for Mental
Wellbeing®

Medication Matters

Causes and Solutions to Medication Non-Adherence

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Introduction

National Council Medical Director Institute

The National Council for Mental Wellbeing is the largest organization of mental health and addictions treatment programs in the U.S., serving 10 million adults, children and families with mental health and substance use disorders (SUDs). In this capacity, it performs important organizational, educational and advocacy functions and serves as a unifying voice for the 2,900 member organizations. The National Council is committed to all Americans having access to comprehensive, high-quality care that affords every opportunity for recovery.

In 2015, the National Council Board of Directors commissioned the Medical Director Institute (MDI) to advise National Council members on best clinical practices and develop policy and initiatives that serve member behavioral health organizations and their constituent clinicians and the governmental agencies and payers that support them.

The Medical Director Institute is comprised of medical directors of organizations who have been recognized for their outstanding leadership in shaping psychiatric and addictions service delivery and draws from every region of the country. One of the ways the MDI fulfills its charge is by developing technical documents that highlight challenges at the forefront of mental health and addictions care, providing guidance and identifying practical solutions to overcome those challenges.

Medication Non-Adherence — Introducing the Topic

Psychotropic medications have produced life-changing benefits for millions with mental and substance use disorders, greatly reducing the global disease burden over the past 70 years. Evidence for the effectiveness of these medications is extensive and incontrovertible. But, as noted by former Surgeon General C. Everett Koop, "Medications only work in patients who take them."

Low levels of adherence to prescribed medication is a national (and international) problem and limits effective health care services. For people with chronic medical illnesses, medication non-adherence substantially adds to disease burden and leads to poorer long-term health outcomes. As a result, this problem has drawn the attention and concern of providers, insurers, policymakers and researchers for decades.

While adherence to pharmacotherapy is a critical element in effective treatment of mental disorders, the key components of excellent psychiatric and addiction treatment extend well beyond compliance and include a strong commitment to patient-centered and recovery-oriented care, in which patients and providers view adherence as a means to an end, not the end in itself. As Patricia E. Deegan wonderfully articulates, "The concept of compliance can't begin to capture the skill building required to learn to use psychiatric medications as a tool in my recovery."²

Best-practice standards endorse treatment planning based on patient-centered recovery and rehabilitation that includes goals developed by the patient and provider that are broader than mere adherence to prescribed medications and may include the patient's choosing not to take the medication recommended by the provider. This approach, preferably delivered by trained interdisciplinary teams, enhances patient trust, engagement, retention and health outcomes, while promoting treatment adherence and recovery. At the same time, the provider must balance the patient's expression of choice, even when it is not to follow the prescribed treatment medication. This must also be balanced with the clinician's assessment of the patient's danger to self or others without medication.

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Published studies aimed at both broadening our understanding of the causes and circumstances of medication non-adherence and improving adherence have been the subject of more than 40,000 journal publications.³ Yet, despite strong interest and extensive research, as well as significant advances in clinical practices such as improved access to and administration of medication, increased involvement and support from providers including pharmacists, sharing of information through e-prescribing and more sophisticated systems that prompt patients, non-adherence continues to be a major problem in terms of frequency and consequences, and remains a therapeutic challenge.⁴

The problem of non-adherence has been highlighted by widely known health care policy and research organizations, including National Quality Forum's National Priorities Partnership, World Health Organization (WHO) and the Network for Excellence in Health Innovation (NEHI), which was previously known as New England Healthcare Institute. NEHI named the solution to non-adherence to all medications "a \$100 billion opportunity."

As health policy adds cost containment to the priorities of improving outcomes and expanding access, non-adherence to prescribed medications has become a significant barrier to achieving the Institute for Healthcare Improvement's Triple Aim: improving the patient's experience of care, improving the health of the population and improving the provider experience and reducing per capita costs of health care.

Non-adherence to medication represents a major problem that limits the effectiveness of treatment and adds to the burden of illness and cost of health care. For these reasons, the National Council undertook development of this report. The paper was completed using the following steps: drafting an outline and problem statement, convening the Expert Panel for a two-day meeting, compiling literature, completing a first draft, soliciting Panel feedback and updating the narrative for a final draft.

The Medication Adherence Expert Panel Process

The Medical Director Institute convened a wide-ranging group of clinicians, administrators, policymakers, researchers, innovators, educators, advocates, peer specialists and payers for a two-day meeting focused on in-depth review and analysis of treatment adherence that integrated multiple perspectives. (See Expert Panel on page 52 for a full list of participants.) The agenda was structured to vet relevant content and build consensus through discussion and debate. The meeting resulted in practical solutions that meet the test of feasibility and effectiveness based on the conclusions of the Expert Panel.

The participants were selected to provide a broad range of perspectives and expertise working with individuals with mental illness and substance use disorders. Panel members provided input from their practical experience and research from their area of expertise for consideration, as well as their unique perspectives on the problem of medication non-adherence.

A technical writer and co-editors served as recorders for the proceedings, compiled the literature submissions from the Panel members and drew on other sources for the background material. While we did not perform a comprehensive literature review or utilize a formal scoring system that weighted each publication or source of information, we synthesized what we believe are the key points, best substantiated and consistent findings across the literature, while relying on the consensus of the Panel members for areas with less empirical research. We chose this approach because the report is intended to provide guidance to policymakers, managers, clinicians and advocates who must routinely make decisions in areas with limited evidence.

The co-editors and technical writer completed a first draft and hosted two conference calls for the Panel members to discuss the paper. They solicited written comments and feedback on the first draft before the final document was completed.

The National Council's goal in producing this paper is to provide information and describe strategies to a wide range of stakeholders; these strategies are intended for implementation in spheres of influence across the behavioral health field, including the Centers for Medicare and Medicaid Services (CMS) and the Substance Abuse and Mental Health Services Administration (SAMHSA); provider organizations; professional trade organizations for psychiatrists, nurse practitioners, physician assistants and pharmacists; consumer and family advocacy groups; insurers of behavioral health benefits; pharmaceutical manufacturers; pharmacy benefit managers (PBMs); state mental health authorities; and policymakers in the behavioral health arenas.

This report includes an environmental scan, summary problem statement, solutions based on research and experience in the field and actionable recommendations. Since the consequences of non-adherence are devastating for both physical illness and behavioral health conditions alike, this paper covers factors related to non-adherence to all medications, not just the psychopharmacologic. The proposed solutions address the behavioral health field specifically. It is likely, however, that many of these initiatives can be effectively applied in treatment settings that deliver care to people with other chronic conditions.

The scope of this report and its proposed solutions addresses the full continuum of settings where adults receive behavioral health care, from long-term and acute inpatient settings, to emergency rooms, intensive outpatient programs and a wide array of outpatient clinics. Additionally, in recognition of the problems of non-adherence associated with transitions between different settings, this paper focuses on all such transitions, including transitioning from non-clinical settings, like prisons or jails, to community treatment settings. The report does not include medication adherence in children or in settings where staff directly administer every dose of medication to the patients — such as hospitals, nursing homes, jails and prisons — because of the substantial differences in non-adherence risk factors and, in some cases, the extent to which medication adherence is voluntary.

Terminology

The term "adherence" will be used to describe patients' patterns of following the prescribed medication orders, although some literature uses the term "compliance." The authors have chosen the term "adherence" over "compliance" to assert that the decision to take a medication is based on a partnership between patient and prescriber on the medication regimen; "compliance" implies a more passive role for the patient in "complying" with the prescriber's orders.

The report also addresses medication non-adherence for treatment of substance use disorders including medication-assisted treatment (MAT) in methadone maintenance programs and outpatient settings that provide long-acting injectables (LAI) naltrexone or buprenorphine. The term "treatment retention" is often used to describe medication adherence in these settings and will be used in this paper.

The Expert Panel is cognizant of the importance of the terminology used to describe people receiving psychiatric care. Throughout this report, people whose immediate situation is receiving care are referred to as "patients." People with a psychiatric condition engaged in advocacy outside of a direct provision of care situation are referred to as "advocates." People with lived experience who are members of service delivery teams working directly with patients are called "peer counselors" and "recovery coaches."

People whose immediate situation is providing care, including the prescribing and monitoring of medications, are referred to as "providers."

When the report refers to "psychiatric service," it includes a range of services such as assessment, diagnosis, treatment planning, medication management, consultation and the supervision and support of other providers. Along with psychiatrists, psychiatric services are delivered by other health professionals such as advanced practice registered nurses (APRN), physician assistants (PAs) and clinical pharmacists.

Definition and Scope of the Problem

Definition: What is Adherence?

"Adherence to (or compliance with) a medication regimen is generally defined as the extent to which patients take medications as prescribed by their health care providers." 5

Adherence to a pharmaceutical regimen prescribed for treatment of any medical condition is critical to ensuring success in virtually all clinical settings, including hospital, emergency room, nursing home, rehabilitation facility, residential program, community health center, doctor's office or other community setting. Non-adherence leads to poorer treatment outcomes and increased costs of health care delivery. Accurately measuring rates of adherence remains a significant challenge.⁶

Researchers have used a number of direct and indirect methods — including direct observation, patient reports and diaries, manual and automated (MEMS caps) pill counts, measurement of drug (or metabolites) blood levels, prescription refills, assessment of the patient's clinical response and technological devices (biosensors, smartphone and virtual monitors) — all of which have benefits and limitations such as patient inconvenience, accuracy of reporting and the cost of administration and measurement.

The most commonly used measure as the standard reference for rates of medication adherence is the medication possession ratio (MPR). MPR is defined as the number of days' supply of medication a patient has received divided by the number of days' supply needed if the patient uses the medication continuously. Patients are considered "adherent" to prescribed medication when they achieve an MPR of greater than 80 percent, meaning the patient possesses the amount of medication that is sufficient for taking the medication 80 percent of the time within the period measured. Any ratio below that will be considered non-adherent, although in some studies a ratio of 60 to 80 percent may be referred to as "partial adherence." An MPR of less than 60 percent will be considered "non-adherence."

Scope of the Problem

When surveying the body of literature related to medication adherence — clinical trials, disease-specific interventions in the field, studies of clinical practice in a range of clinical settings and meta-analyses and reviews of the studies themselves — a clear and unequivocal finding emerges.

Non-adherence is a significant problem across all health care delivery systems and settings and represents a major public health problem. Thousands of reports of clinical trials, retrospective reviews and meta-analyses across varied diagnostic groups have documented the rates of non-adherence.8

After accounting for many of the variations reflected in the research, most researchers and policy experts generally accept the summary by WHO, which estimates that **up to 50 percent of prescribed medications are not taken**. Buckley, et al., reviewed multiple adherence studies and catalogued the range of reported rates of medication non-adherence rates by chronic conditions (order of conditions below is revised from Buckley to descend from highest reported non-adherence rate to lowest).⁹

Rate of Non-Adherence by Medical Condition

Condition	Rates of Non-Adherence
Asthma	25-75%
Major Depression	51-69%
Diabetes — Oral Meds	7-64%
Schizophrenia	30-60%
Anxiety Disorders	57%
Coronary Heart Disease	40-50%
Bipolar	21–50%
ADHD	26-48%
Diabetes — Insulin	37%
Alcohol Abuse/Dependence	35%
Hypertension	16–22%
HIV	13%

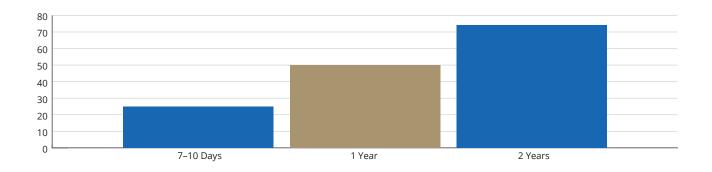
Non-Adherence for Chronic Health Conditions

When measuring non-adherence based on prescriptions not being filled by patients on Medicare, there were higher rates of non-adherence for chronic illnesses such as psychiatric conditions, arthritis, cardiovascular disease and chronic obstructive pulmonary disease (COPD) (measured by statistical significance from the average). When comparing adherence for acute conditions, including acute coronary syndrome, to adherence for chronic conditions, Osterberg reported higher rates of non-adherence for chronic conditions.

Non-Adherence for Mental Health Disorders

Cramer and Rosenheck reported that non-adherence to antipsychotic medications averages 42 percent +/- 19 percent. ¹² For antidepressants, the average rate of non-adherence is 34 percent +/- 18 percent. In addition, non-adherence to antipsychotic medication increases significantly over time, as Vauth's table demonstrates. ¹³

Percentage of Patients Partially Adherent to Antipsychotic Medication



Non-Adherence Rates for Substance Use Disorders

Adherence to medications used to treat substance use disorders is often directly dependent on retention in broader treatment programs, particularly for methadone. Individuals who leave a program or are terminated by a treatment program — a decision made by the program, rather than the patient — often lose access to any medications supporting their addictions treatment. A non-adherence rate of 35 percent of patients participating in MAT was reported by Roux.¹⁴ In another study, Timko found that patients with opiate dependence who were receiving MAT with buprenorphine had a retention rate of 34 percent.¹⁵ Two studies have reported that extended release naltrexone is as effective as daily buprenorphine/naloxone after induction in terms of both adherence and treatment outcome.^{16,17} And, in a meta-analysis of studies on retention, there was an average rate of retention of 42 percent overall for methadone.¹⁸

Comparison of Non-Adherence in Chronic Conditions

Reviews of rates of non-adherence for chronic medical conditions compared to chronic psychiatric conditions find no significant differences.¹⁹ When reviewing a series of clinical trials for a range of chronic conditions including hypertension, Osterberg (p. 487) reported rates of medication non-adherence that ranged from 22 to 57 percent.²⁰

Predictors and Causes of Medication Non-Adherence

Predictors and causes of medication non-adherence have been identified from individual clinical trials, meta-reviews of both clinical trials and retrospective analyses of practice. In addition, broader papers addressing policy and program implications related to non-adherence have been published by organizations such as WHO, National Quality Forum (NQF), SAMHSA and NEHI.²¹

Specific causes at the macro-level include a complex delivery system, community demographics, and customs and beliefs — including a stigma about mental illness and substance use disorders and opposition to psychiatry as a profession in which advocates deny or seek to discredit the effectiveness of medications. Causes at the micro-level include individual patient characteristics, provider characteristics, medication regimens and medication side-effects. All these factors can influence adherence separately and in combination. In short, sorting out the multiple causes of medication non-adherence is complex and challenging.²²

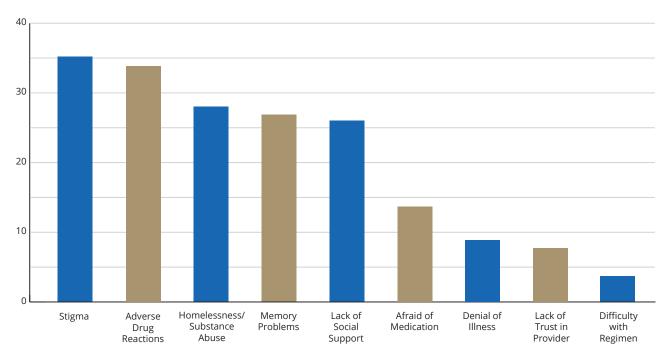
WHO classifies the wide-ranging list of factors into the following four categories which we will use in this discussion:

- Patient characteristics, including family involvement and patient demographics.
- **Therapy-related factors** surrounding the patient-provider relationship within the full context of the patient's treatment plan.
- Specific features of the diseases and conditions that are being treated, including the medication itself.
- The impact of the **health care system** in which the patient-provider relationship takes place on adherence, including the variations of the delivery system based on socio-economic demographics, health care coverage and access to providers.²³

Patient-Related Predictors of Non-Adherence

Patient characteristics including attitude toward their disease and the prescribed medications can have an impact on adherence. Some reasons for non-adherence are listed in the following chart as patient-specific attitudes.

Frequency of Barriers to Medication Adherence in Patients with Schizophrenic Disorders²⁴



Some patients with a low level of health literacy or lack of trust in the provider are less inclined to accept the value of medications and, therefore, have lower adherence to the prescribed medication regimen.²⁵ Non-adherence may also be due to the stigma of having a chronic mental health disorder. Patients without insight into their illness have negative beliefs about the value of medications or believe that once symptoms have dissipated, they no longer need medications typically have low rates of adherence.²⁶ Non-adherence for some patients may also be linked to the delay in the medication's benefits, which may not occur for several days or weeks.

At the other end of the spectrum are patients who have a very high level of health literacy, understanding the positive effect of the medications on their psychiatric symptoms or addiction. Some of these patients may value independence above dependence on psychiatric or MAT medications and prefer to be self-reliant. In this case, non-adherence can result when patients make a conscious choice to reduce or discontinue medication when adherence interferes with more important goals for recovery.²⁷ This occurs when provider treatment goals are not consistent with patient treatment goals.

In short, the goals of treatment extend beyond adherence with medications and encompass a strong commitment to patient-centered, recovery-oriented care. Patients view adherence as a means to an end, not the end in itself. As Patricia E. Deegan wonderfully articulates: "The concept of compliance can't begin to capture the skill building required to learn to use psychiatric medications as a tool in my recovery." 28

Finally, higher rates of non-adherence occur in patients with comorbid psychiatric conditions and active substance use. ^{29,30}

Patient-Family Factors Impacting Adherence

Families can help patients be adherent by providing practical support and reminders as well as understanding how medications have helped their loved ones and conveying this information in a way that patients can relate to and understand.

At the same time, some patient-family disagreements and conflicts can reduce adherence. This typically occurs when the patient's goals and the family's goals do not align — much like the divide between patients and providers when goal articulation and mutually respectful decision-making do not occur.

The balance between educating and involving the family and respecting the patient's autonomy and goals for recovery can be difficult to manage and maintain. Finally, a family's belief that prescribed medications are not effective and its desire to avoid the stigma of mental illness or addiction can influence the patient's beliefs and behavior, resulting in non-adherence.

Relationship and Communication Factors That Result in Higher Rates of Non-Adherence

The provider-patient relationship is a key variable in medication adherence.³¹ Results from assessments of the nature of the relationship, specific elements of the patient-prescriber relationship and the skills of the prescriber point to several predictors.

First, poor communication between the psychiatric/MAT provider and patient, defined in several ways, can lead to non-adherence.³² For example, higher rates of non-adherence are associated with a provider's failure to collaborate with the patient to agree on treatments and explore how medication is integrated with patient-centered goals.³³ Second, if the provider does not have information from an assessment of risk factors for non-adherence and erroneously develops expectations of high adherence, the discussion may not include or have limited exploration of barriers to adherence and thus fail to explore potential solutions. Third, a provider's lack of knowledge about adherence and effective interventions can exacerbate non-adherence.³⁴ Finally, the prescriber can simply fail to recognize non-adherence.³⁵

The Nature of the Medication

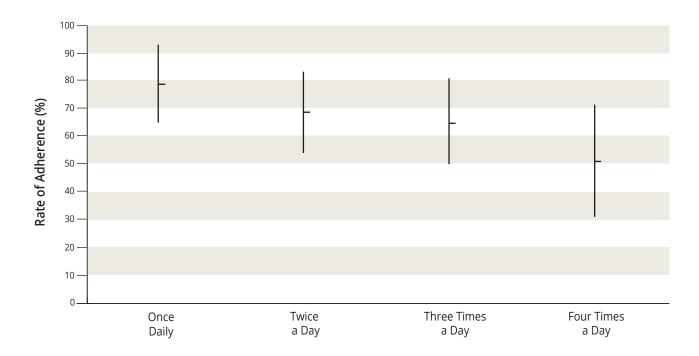
Medications themselves, while functioning to stabilize the course of chronic conditions and increase chances for recovery and health, often have unpleasant side-effects (including weight gain, neurologic effects, sexual dysfunction, sedation, constipation and cognitive impairment) that can be the impetus for non-adherence.³⁶ Lists of extensive side-effects on package inserts or websites can be frightening and contribute to reticence about treatment adherence.^{37, 38} When the illness or medication effects include cognitive impairment, denial and lack of insight can be facilitated, further limiting the capacity of the patient to understand the value of the medication and follow the regimen.

The details of the prescription regimen can be "patient unfriendly." Medication requirements that are considered patient unfriendly include increasing the number of times during the day that medication is taken, frequent changes of a regimen, required changes in diet, inconvenience in administration, requirements to master techniques such as injections, tablet size and difficulty in opening containers.³⁹

The more frequently a medication must be taken, the lower adherence to the regimen is likely to be.⁴⁰

The increased sophistication of diagnostic procedures and proliferation of medical specialties have resulted in an increasing number of medications for complex conditions. These changes in practice have doubled the number of people receiving five or more medications between 2002 and 2012. This increased level of complexity can lead to information overload, resulting in patient's confusion about how best to organize their schedule and living arrangements in relation to taking medications. Furthermore, without proper information, subsequent prescriptions may be contraindicated by current prescriptions, reducing the effectiveness of the medications at best and putting the patient at higher risk at worst — both situations can lead to non-adherence.

Medication Schedule



Other patterns of the medication regimen that reduce adherence include:

- · Increasing the number of medications in a regimen.
- Dispensing medications individually, as opposed to combining all pills taken at one time in a bubble pack or a daily pill container.
- Medication side-effects. 42

Factors Associated with Health Care Delivery System

The process for obtaining a medication can be simple or complex based on insurance coverage; ease of obtaining authorization; alignment among prescriber, pharmacist and patient; and availability of medication. Often, hospital drug formularies operate independently of community pharmacy and payer formularies, setting up a discontinuity between medication prescribed during an inpatient visit and that accessed through an outpatient provider. The challenge also includes sharing the information from the hospital provider with the pharmacy and outpatient prescriber. In the May 14, 2017, *NEJM Catalyst*, it was reported that only 20 percent of hospitalists communicate with the primary care provider after inpatient discharge, minimizing the sharing of crucial information about changes in medication.⁴³ Implementing "medication reconciliation" around transitions of care from inpatient and emergency department levels of care to community settings addresses the need for improvement. Medication reconciliation can be an appropriate tool to harmonize drug regimens when there is a change in levels of care or significant change in therapy. Failure to schedule timely follow-up appointments after discharge inhibits the patient's ability to maintain adherence and poor discharge planning can interfere with adherence in the transition of care between one setting, such as inpatient or emergency department and the outpatient settings.^{44, 45, 46}

Predictors and Causes of Medication Non-Adherence

Another barrier to adherence can arise when payers restrict their drug formulary or change the formulary, limiting access to certain medications or complicating the prescribing process.⁴⁷ The nature of the formulary may also involve expensive co-pays that reduce chances of refill.⁴⁸ In addition, traditional practices involving prior authorization review can impede timely access to a prescription.

Even when authorization is secured, delays in the process can affect the provision of other important services to the patient. The more time providers must spend obtaining prior authorization, the less time they have for building the understanding and trust necessary for good medication adherence.

Patients are often required to change their pharmacy benefit annually, even if they stay with the same pharmacy benefit manager, preferred medications are often changed annually and the resulting disruptions and access problems increase medication non-adherence. Patients' adherence, evaluated by the MPR and persistence in treatment, decreases with an increase in the frequency of generic substitutions when there is no change in cost to the patient.⁴⁹ However, adherence increases when switching from brand to generic medication reduces cost to the patient.⁵⁰

Changing the appearance of a medication can confuse patients and increase non-adherence. In the largest study of its kind, researchers from the Brigham and Women's Hospital in Boston examined the impact of drug color on the pill-taking habits of more than 10,000 patients "who had been hospitalized after a heart attack between 2006 and 2011." The study found that the odds that patients would stop taking a drug or fail to refill a prescription jumped dramatically when they went for a refill and the color or shape of their generic pills changed: 34 percent for a change in pill color and 66 percent for a change in shape. 51,52

Cost Factors Related to Medication Non-Adherence

Out-of-pocket costs for medications, even covered medications, can be prohibitive, leading to non-adherence. But providers are unable to ascertain the out-of-pocket costs of medications on their own and, due to variances in insurance formularies, what is inexpensive for one group of patients may be quite expensive for others. Patients who discover that a medication has prohibitive out-of-pocket costs after they leave the provider's office may not disclose this to the provider until the next visit. Even then, they may be embarrassed to reveal that they didn't take a medication because of its cost, or they may blame the provider and choose not to return without revealing why. Pharmacy personnel often are unable to provide the out-of-pocket costs for medications until they have run a formal prescription transaction through the system, creating unnecessary work for all concerned. The high cost of many medications leads pharmacy benefit plans (PBPs) to implement prior authorization procedures, generic switching requirements and frequent formulary changes — all problematic, as previously noted.

Predictors and Causes of Medication Non-Adherence

Socio-economic and Other Predictors

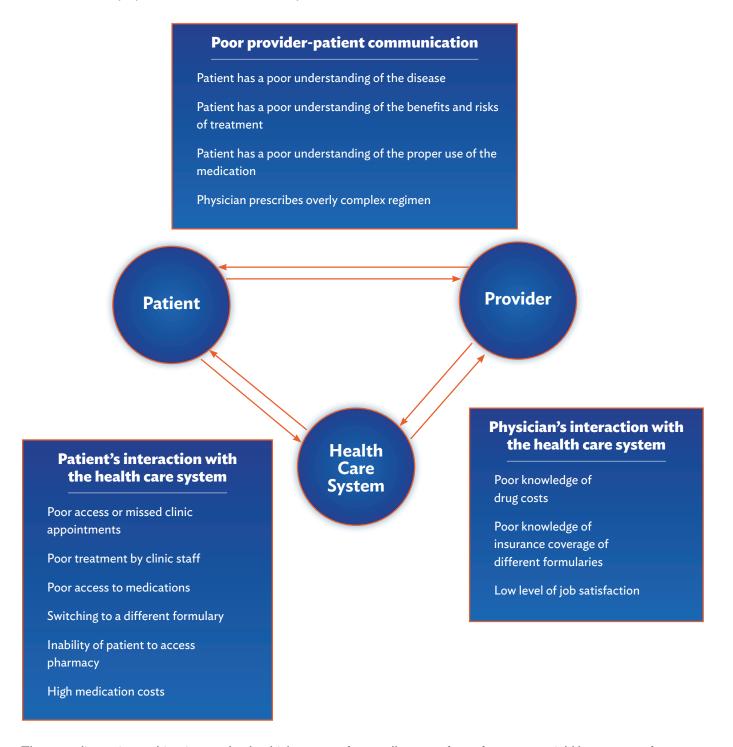
A variety of social, economic and other factors can contribute to lower rates of medication adherence. These include:

- Lower socio-economic status (SES).53
- Variation in the customs, beliefs and background of provider and patient.⁵⁴
- Lack of sensitivity to the patient's personal opinions about mental Illness and their customs and beliefs regarding medication.⁵⁵
- Cost concerns for a refill of medications for patients from a lower SES resulting in a higher rate of not filling prescriptions.⁵⁶
- A poor social environment that offers few if any supports for adherence to the MAT regimen can lead to substance
 use of opioids and alcohol and cessation of MAT.⁵⁷

Conflicting views covered in the media about the nature of mental illness and addiction and the effectiveness of medication in treating these disorders can create confusion and misunderstanding and encourage ambivalence toward medication, increasing the potential for non-adherence.

Summary of Interaction Among Predictors of Non-Adherence

In short, the interplay of all these variables is complex.



These predictors in combination can lead to higher rates of non-adherence; fewer factors may yield lower rates of non-adherence.

Predictors and Causes of Medication Non-Adherence

Adherence Varies Over Time

Another way to view these complex interactions is the unique perspective of the patient. Patients can make implicit or explicit calculations of the cost/benefit of relief of symptoms versus the side-effects of powerful medications such as chemotherapy for cancer treatment, HIV medications and antipsychotic medications. A patient's reaction to this cost/benefit "decisional conflict" (Deegan) is not static; it can vary day to day, week to week and month to month, resulting in periods of adherence followed by periods of non-adherence.

Researchers have reported the impact of non-adherence in two ways: studies on specific clinical populations and disease conditions that measured outcomes associated with medication and meta-analyses of past studies that grouped common variables from all the studies that were reviewed. The result is a wide range of documented impacts of non-adherence that include treatment failure, risk of hospital admission and re-admission, relapse, increases in the total cost of care by condition and cost increases in the health care system overall. Within the field of behavioral health, there are additional impacts related to non-adherence on the relationship between provider and patient, family and patient, and provider and community. Non-adherence to medications for behavioral health conditions also has social impacts in the form of homelessness, incarceration and violence.

The Expert Panel endorses achievement of the Institute for Healthcare Improvement's Triple Aim, the vision for health care delivery: improved patient outcomes, better patient experience with the health care system and reduced costs of delivering care. Patient non-adherence to medications has serious impacts on each of the three pillars of the Triple Aim.

Adverse Outcomes of Non-Adherence: Relapse, Hospitalization, Risk of Suicide, Illness Progression and Disability

Numerous studies have demonstrated the various consequences of medication non-adherence. These include psychotic relapse; the need for hospitalization and risk of suicide; interruption of education, work activities and social relationships; and potential progression of illness.

Treatment non-adherence is also identified as a frequent reason for hospitalization and suicide in bipolar patients.^{58, 59}

Impacts of Non-Adherence on Chronic Health Conditions

Medication non-adherence is a significant barrier to improved health outcomes for many chronic conditions. For individuals with schizophrenia, the chances of relapse increased from 35 percent for adherent patients to 75 percent for non-adherent patients, while non-adherence was shown to account for 33 to 70 percent of hospital readmissions. ⁶⁰ Non-adherence increases the chances of hospitalization and is correlated with higher rates of hospitalization. ⁶¹ A NEHI study showed that non-adherence led to an increased risk of hospitalization for diabetes, while also summarizing evidence that the mortality rate for heart disease and diabetes was 12.1 percent for non-adherent patients compared to 6.7 percent for adherent patients. ^{62,63}

Numerous studies have found large differences in life expectancy (approximately 20 years) of people with schizophrenia in relation to non-serious mental illness (SMI) populations. Shortened survival is multifactorial, with suicide accounting for substantially less excess mortality than excess medical co-morbidities (cardiovascular and respiratory disease, diabetes and substance abuse). Studies conducted in Finland and Scandinavian countries have found significant correlations between adherence to antipsychotic medications and greater longevity.⁶⁴

Reviews of the clinical impact of non-adherence include findings that medication non-adherence accounts for 30 to 50 percent of treatment failures and 10 to 25 percent of all hospital and nursing home admissions (ACPM, p. 4).^{65, 66}

Medication non-adherence alone increases the chances of admission by 40 percent and has increased utilization of hospital emergency departments.^{67,68} A NEHI study reports that 89,000 premature deaths could be avoided with adherence to appropriate medication treatment.⁶⁹

Impacts of Non-Adherence on Provider-Patient Relationship

Clinicians generally overestimate their own ability to identify and quantify non-adherence among their patients, highlighting the importance of objective and validated approaches to measurement.⁷⁰ A study found that clinicians' best estimate of the proportion of their outpatients who missed 30 percent or more of their medication was approximately 6 percent, while an electronic device in the cap of the medication bottle suggested that approximately 60 percent of the same patients met this threshold for non-adherence.^{71,72}

Adherence is a key component of the provider-patient relationship and, like other forms of advice and treatment, the success of the patient's follow-through can have an impact on the overall relationship. In fact, research on measuring adherence as a variable has shown that patients often overstate adherence because they fear disappointing the psychiatric provider, just as providers have been shown to overestimate the patient's adherence.⁷³

Psychiatric provider's misjudgment can lead to further inaccurate attributions of the patient's clinical presentation and result in increased dosages or additional medications, which may exacerbate the side-effects and further reduce the patient's commitment to adherence and the potential solutions. The over-emphasis on medication adherence in the provider-patient relationship distracts attention from the patient's broader goals for recovery.⁷⁴ A growing gap in genuine exchange on the degree of adherence decreases the chances of a stronger rapport between patient and prescriber as noted by Butterworth.⁷⁵

Social Impacts of Non-Adherence to Psychiatric Medications

Treatment non-adherence can lead to several onerous social consequences including homelessness, people with mental illness being incarcerated in prisons and random and large-scale violence. The reason for this problem is that the symptoms of mental illness particularly psychotic symptoms, can impel people to harm themselves.

The nature of SMI often includes impulses for patients to harm themselves or others. While most patients rarely act on these impulses, non-adherence to medication greatly increases the chances of harm to others which can also increase arrests and imprisonment for threatening or harming others. The ready access to firearms increases the risk of great harm. For example, a large prospective multisite study that included 1,906 patients revealed that non-adherent patients were more than twice as likely to be violent as adherent patients. They were also more likely to be arrested than adherent patients (8.4 percent versus 3.5 percent).

Medication-Assisted Therapy Non-Adherence and Social Impact

Non-retention in medication-assisted programs leads to lower job productivity, absenteeism and increased presenteeism. For certain populations, non-retention can lead to a return to criminal behavior to obtain opiates.

Non-Adherence and Outpatient Commitment Laws

The social consequences for non-adherence to pharmacotherapy, as well as its deleterious effects on patients with psychotic disorders, has prompted greater interest in mechanisms to enhance medication adherence even in the face of patient recalcitrance. Outpatient commitment, also known as assisted outpatient treatment (AOT), is defined as "medically prescribed mental health treatment that a patient receives while living in a community under the terms of a law authorizing a state or local court to order such treatment." (SAMHSA definition of AOT at https://www.samhsa.gov/sites/default/files/grants/pdf/sm-16-11.pdf). This is also known as involuntary outpatient commitment and other terms and involves petitioning local courts to order individuals to enter and remain in community based treatment for a specified period of time⁷⁸ to prevent relapse and dangerous deterioration.

Forty-six states now have some form of AOT law, but implementation and use are widely varied and many states have low AOT utilization. Enforcement by local law enforcement is problematic in some jurisdictions. Lack of adequate funding for court-ordered treatments impedes implementation. Research into AOT programs has shown that these laws are most effective when combining intensive community services and a court order over a sustained period, ideally at least 180 days. Service intensity requirements are usually met by using assertive community treatment teams or intensive case management services. Assisted outpatient treatment is currently the subject of large-scale federal multisite research, focusing on what treatment, legal and other factors lead to the most effective use of these programs.

Impacts on the Costs of Delivering Health Care

Both the American College of Preventive Medicine (ACPM) and NEHI estimate that non-adherence adds an economic burden of \$100–300 billion per year to the health care system and state that non-adherence has dramatically raised the cost of health care due to illness exacerbation.^{79, 80, 81} When comparing the total cost of care of treating diabetic patients with poor rates of medication adherence to the cost of treating adherent patients in the same paper, NEHI noted that the cost is nearly two times higher for the non-adherent population.⁸²

For individuals with non-adherence, the resulting lack of efficacy leads to increased hospital, emergency room and outpatient care utilization. The apparent lack of efficacy of medication monotherapy with the usual dose because of unidentified non-adherence can result in either inappropriately higher doses or unnecessary polypharmacy, both of which increase pharmaceutical costs.

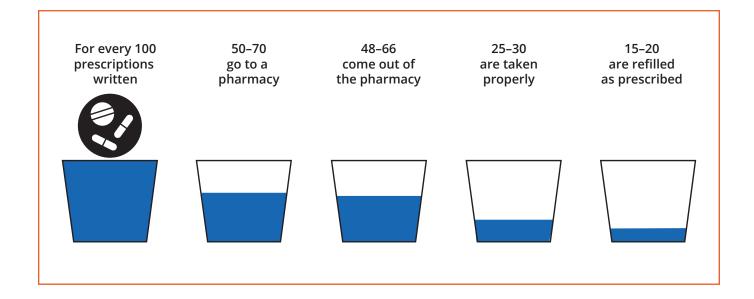
Delivering cost-effective care is one of the three fundamental goals of the Triple Aim. Medication non-adherence presents a major obstacle to success in that effort.

Conclusions

Non-adherence is a major barrier to improved health outcomes for many chronic and acute medical conditions. The problem has been well-documented and studied — from population and disease-specific clinical trials, to meta-analyses of hundreds of studies, to reviews of large populations.

Non-adherence affects outcomes through increased chances of relapse, hospitalization, use of emergency room, lifestyle disruption, nursing home placement, illness chronicity and premature death. It impacts the efficiency of the health system through more frequent use of high-cost services, additional prescriptions to offset non-adherence and remedial interventions to address relapse. The added cost of non-adherence to the health care delivery system is estimated at between \$100 and \$300 billion. And non-adherence affects patients, families and communities, through increased risk of suicide, homelessness, imprisonment, violence to others and the trauma of large-scale violence.

The phenomenon can be summarized with the following graphic:



Solutions

Principles for Solutions

The previous sections described an array of risk factors for medication non-adherence, then examined the impacts of medication non-adherence on individuals and the systems of health care and support surrounding them. This section presents interventions and practices from published literature that can begin to address the causes of non-adherence and reduce the deleterious impacts on patients. These solutions are organized in recognition and acceptance of the following principles:

1. Substantially improving medication adherence will require multiple solutions involving multiple participants, including:

- a. Patient
- b. Prescribing provider organization and the staff supporting the provider and patient
- c. Pharmacist
- d. Payer
- e. Pharmaceutical industry
- f. Patient's family
- g. The larger health delivery system

2. No single solution will be adequate.

Multiple participants must hold themselves accountable for implementing their part of the solutions.

3. There is stigma associated with mental illness and psychiatry.

The lack of understanding by the public, government and media is an aspirational goal to address by increasing public awareness. It is essential that the public, government and media understand that mental disorders are true illnesses which impose a burden of suffering and cost to affected individuals, their families and society, and for which effective treatments exist.

4. Improved relationships between provider and the patient improve rates of adherence.

Findings on medication adherence across treatments for all chronic health conditions indicate that poor patient-provider communication causes low adherence. This calls for behavioral health providers to establish relationships as a best-practice model for other providers.⁸³

5. Medication adherence is a multi-step process.

- a. The provider and patient come to a shared understanding of the benefits and risks of medication, considered in the context of the patient's values and preferences. Medication is prescribed if they agree that the benefits both outweigh the risks and contribute to the patient's goals for recovery.
- b. Both the provider and patient formally assess the patient's history, approach and personal process for taking medication.
- c. The provider sends an accurate order for the medication to a pharmacy.

- d. The medication is available for the pharmacy to dispense, the patient has access to pharmacy services and they can obtain the medication from the pharmacy.
- e. The medication is administered as ordered.
- f. All participants are aware of the extent to which adherence is occurring.
- g. All participants continuously monitor adherence and adjust routines to address the expected variations in adherence that will occur periodically.

6. Interventions must be prospective and measurable.

The immense volume of studies has demonstrated the problem across treatment for most, if not all, chronic health conditions. Any organization seeking to improve adherence must establish measures of improvement and operate prospectively.

7. Improving medication adherence will require widespread commitment

The Institute seeks to align with the policy goals and pronouncements of health care leaders across a broad spectrum of health care delivery. NQF, WHO, Institute for Healthcare Improvement (IHI), SAMHSA and NEHI all highlight improved adherence as a key priority for their organizations.

8. Improved adherence improves health outcomes.

9. Improved adherence saves money.

It has been estimated that every dollar spent on medication adherence saves \$4 to \$7 in costs for the treatment of non-adherence in chronic conditions.⁸⁴ Efforts to improve adherence will have the greatest impact for patients and patient populations at the highest medical risk whose health care costs overall are the highest. The Pennsylvania Project demonstrated that targeted efforts are the most effective and had the most dramatic improvements in adherence for patients with chronic diseases.⁸⁵

Solutions

1. Improve communication between provider and patient.

A key finding on adherence to medications for chronic medical illnesses was the impact of poor communication between patient and provider. Providers tend to overestimate rates of adherence, while patients overreport adherence.^{86,87} Concrete solutions exist to improve that communication.

Shared decision-making

Patients struggle with the challenges of adherence to a complex regimen and have difficulty coping with the sometimes-debilitating side-effects that can interfere with broader goals.88 SDM focuses on both the decision about whether to take medication and on which medication to take. While this sometimes leads patients toward a decision not to take medication, SDM allows patients to be active participants in their care and to articulate the role of medication in their goals for recovery.89

This process also can address patients' preferences for how to be adherent, as well as any self-identified risks or triggers for non-adherence. Intake assessments can include a survey of patients' experiences with taking past medications, including previous incidents when adherence was an issue. Goals established by providers relating to improved adherence must be incorporated into broader goals for health and recovery defined by the patient and based on the patient's strengths, needs, aspirations and preferences.

Motivational interviewing

Motivational interviewing (MI), which focuses on behavior change, can be very helpful in promoting adherence once the goal of medication administration has been collaboratively established and it improves the patient-prescriber relationship, as noted in the literature on improving adherence for patients with chronic medical conditions.

Motivational interviewing is non-judgmental, non-confrontational and non-adversarial. The approach attempts to increase the client's awareness of the potential problems caused, consequences experienced and risks faced because of the behavior in question. Alternatively, or in addition, therapists may help clients envision a better future and become increasingly motivated to achieve it. Either way, the strategy seeks to help clients think differently about their behavior and ultimately to consider what might be gained through change. Motivational interviewing focuses on the present and entails working with a client to access motivation to change a particular behavior that is not consistent with a client's personal value or goal. Warmth, genuine empathy and acceptance are necessary to foster therapeutic gain (Rogers, 1961) within motivational interviewing. Another central concept is that ambivalence about decisions is resolved by conscious and unconscious weighing of pros and cons of changing vs. not changing.

The main goals of motivational interviewing are to engage clients, elicit change talk and evoke client motivation to make positive changes.

Practitioners must recognize that motivational interviewing involves collaboration not confrontation, evocation not education, autonomy rather than authority and exploration instead of explanation. Effective processes for positive change focus on goals that are small, important to the client, specific, realistic and oriented in the present and/or future.

Key aspects:

Motivation to change is elicited from the client and is not imposed from outside forces.

It is the client's task, not the counselor's, to articulate and resolve the client's ambivalence.

Direct persuasion is not an effective method for resolving ambivalence.

The counseling style is generally quiet and elicits information from the client.

The counselor is directive, in that they help the client to examine and resolve ambivalence.

Readiness to change is not a trait of the client, but a fluctuating result of interpersonal interaction.

The therapeutic relationship resembles a partnership or companionship.

Motivational Interviewing Network of Trainers90

MI transforms the frame of the conversation from "non-adherence" to that of a temporary interruption in the prescription regimen, confusion in the home, occasional forgetfulness, fear of stigma or need for a respite from side-effects. He skills presume that there will be some resistance by the patient to a path of ready acceptance of a treatment plan that includes medications in addressing a clinical problem. The skill of the provider consists of interviewing techniques that foster a willingness to find common ground on goals and potential positive outcomes,

acceptance of the patient's point of view and belief system and naming the patient's stage of readiness to change. In this framework there is a greater chance of a non-judgmental discussion around the topic of non-adherence, rather than associating it with treatment failure.

Successful interventions in the application of MI include several instances of pharmacists being trained in MI skills under medication therapy management (MTM) programs initiated by PBMs in the Medicare Shared Savings Program.⁹²

Medication therapy management (MTM) is medical care provided by pharmacists whose aim is to optimize drug therapy and improve therapeutic outcomes for patients. MTM services target beneficiaries who have multiple chronic conditions and take multiple medications. Medication therapy management includes a broad range of professional activities such as formulating a medication treatment plan, monitoring efficacy and safety of medication therapy, enhancing medication adherence through patient empowerment and education, and documenting and communicating MTM services to prescribers to maintain comprehensive patient care.

2. Assess the risk of medication non-adherence.

An assessment of the factors that can put the patient at greater risk for non-adherence can reveal many practical solutions to improve adherence. Most solutions ease the burden for the patient, although not always without additional costs.

The key to providing the most effective intervention is to match the specific solution to the patient's individual needs developed from a thorough assessment, which includes:

- a. Looking for opportunities to eliminate unnecessary or redundant medications. Minimizing the number of medications taken will increase adherence.
- b. Looking for opportunities to reduce the frequency of medications, the fewer times each day medication must be taken, the better adherence will be.
- c. Assessing the storage, accessibility and visibility of medications. Visual reminders and clues are a key strategy to improving adherence, e.g., putting medications in the path of something else the patient would be doing that time of day, like brushing teeth.
- d. Assessing the time and physical burden of taking the medications. Medication adherence is much easier using bubble pack dispensing or a pillbox.





Bubble packs, also known as compliance packs or blister packs, help people keep track of their medicines. Bubble packs contain designated sealed compartments or spaces for medicines to be taken at particular times of the day. Each order is custom-filled and individually labeled for the patient.

Organized by date and time

Each pack is clearly marked with the date, day of the week and simple icons alerting the patient to the next dose — morning, midday, evening or bedtime.

Timesaving

A 30-day supply of multi-dose packs means fewer trips to the pharmacy and less time organizing multiple bottles and pillboxes.

Convenient

The bubble pack holds all medications in one place. Packs are convenient and portable.

- e. Assessing whether the patient has help from others in taking medications. Patients with assistance have better medication adherence.
- f. Assessing the reasons for missing doses of medications, which can be voluntary. Understanding why someone misses a dose and determining if the pattern is episodic or routine can help patients and providers craft more effective solutions that are consistent with the actual problems that patients experience.

3. Match provider interventions and medication regimen to patient's individual needs.

Demonstrating receptiveness to patients' perspectives on the challenges they face around taking medications. Working with them to design solutions and, when successful, acknowledging success, will improve communication and can lead to behavioral change related to improved adherence and higher attendance at scheduled appointments. ^{93, 94, 95} The skill for the provider is to identify the patient's perspective on adherence and discuss challenges and successes openly to encourage a partnership in addressing the acknowledged challenges.

Matching the intervention to the individual requires context-aware providers to assess individual needs of patients with varied backgrounds and beliefs about medication and health care overall. A workforce skilled in context-aware assessments is the first step in assessing risk and identifying solutions that are consistent with the patient's customs and beliefs, especially fears of health care institutions and lack of health literacy. A related solution is the identification of the patient's natural community supports that can be a resource for supporting adherence, just as those supports can improve rates of no-shows to clinic appointments.

4. Encourage utilization of long-acting injectables.

The use of LAIs, formulations that are available for certain clinical presentations, substantially improves medication adherence and offers the convenience of an injection monthly or less frequently. Administering medication by LAI results in more constant serum levels without the high spikes associated with side-effects and low troughs associated with loss of efficacy experienced with oral medication. Subsequent reduction in side-effects further improves adherence. LAIs also have the potential to impact the chronic course of SMI when administered in the right dosage early in the course of illness and put the patient on a quicker path to recovery than conventional methods. LAIs have been shown to be effective in reducing relapse, hospitalization and even incarceration. Thus, the use of LAIs, in itself, is a solution to improve adherence. The substantially improves medication in the substantial presentation in the

However, the promise of expanded adaptation has not realized its full potential. Using the strategies of SDM and fully informing patients of the benefits and risks can help patient, provider and family make an informed decision around goal-setting and attainment. First, LAIs should be presented as a useful strategy when seeking stabilization of symptoms while removing the daily routines required for taking oral medications. This begins with choice of language — identifying the recommended prescription as "long-acting medications" (LAMs), which are administered by injection, rather than "long-acting injectables." Using the term "injection" before discussing the benefits often distracts the patient from the presentation of the benefits. (Comparisons with long-acting injected medications in primary care, such as Depo-Provera for contraception, might also help diminish the stigma of an injection for a mental illness.)

Providers can develop skills presenting the option of a LAM around the relief of the burden of daily pills, diminished frequency of visits to the physician and pharmacy and lower total dose with fewer side-effects, in contrast to the peaks and valleys of mood, discomfort and effectiveness of a daily regimen involving pills. With less time and attention to medications, the patient is freed to pursue activities related to recovery, rehabilitation, family support and community involvement.

Before administering the LAM, the oral form of the medication should be tried to ensure that patient tolerates the medication. The LAM is then administered gradually at a dose lower than the equivalent target dose and is supplemented by oral medication in a process of cross titration. This procedure is well-documented, widely used and minimizes the chance of serious and distressing side-effects.

Another requisite for expanded use of LAMs is improving the skill of the provider and team in administering the injection. Lack of confidence in the provider will translate to uncertainty in the patient. Some providers hire nurses exclusively to administer the injections promptly, efficiently and safely with a minimum of discomfort for the patient. This is a resource, but the same outcome can be attained by providing the medical staff with training in administering injections.

5. Medication selection based on efficacy and side-effects.

Choice of medication should be informed by individual patient needs in terms of target symptoms and side-effect sensitivities. ⁹⁸ In this context, special consideration should be given to clozapine because of its superior efficacy against psychotic symptoms, suicide, substance use and violence — all of which contribute to enhancing treatment adherence. On the other hand, patients in their first psychotic episode or early in their course of illness often are more sensitive to medication effects and thus require lower doses to achieve therapeutic effects; they also are more sensitive to side-effects, which can lead patients to be non-adherent. Consequently, consideration should be given to medications that have side-effects that are better tolerated.

6. Send an accurate order for the medication to a pharmacy.

E-prescribing improves adherence, reduces prescription errors and saves time for the patient, prescriber, clinic staff and pharmacy. Computerized order-entry prevents errors secondary to misspelling medications or the prescribing of dose forms that are not available or inappropriate. Electronic transmission eliminates errors due to transcription by nursing staff or pharmacy from the original physician orders and ensures that all prescriptions arrive at the pharmacy and are ready for pickup immediately upon patient arrival. More than 80 percent of patients prefer e-prescribing. Multiple studies show that e-prescribing improves adherence.

7. Improve patient's access to pharmacy services.

Establishing pharmacies onsite within mental health clinics will improve adherence compared to clinics without pharmacies onsite. A recent study published in the *Journal of Managed Care & Specialty Pharmacy* compared data from two community mental health centers with onsite pharmacies to see if there were differences in medication adherence and outcomes between patients who used the onsite pharmacies and those who used community pharmacies. The results indicated significantly higher rates of medication adherence, as well as lower rates of behavioral health-related hospitalizations and emergency department visits, representing an impact on reducing total cost of care.⁹⁹

Improved adherence rates among patients using onsite pharmacies have been attributed to multiple factors, including convenience, the collaborative relationship between pharmacists and clinic staff and specialized services that may not be offered at community or mail-order pharmacies. Such services include specialized packaging, medication synchronization, refill reminder calls, clozapine monitoring and education.

MCOs and other payers can play a role in improving medication adherence by removing some of the barriers to authorization. Currently, the obstacles to matching medications to needs involves over-use of "step therapy," in which patients must demonstrate "failure" of one medication before a costlier medication is approved. Another obstacle is the time-consuming prior authorization procedures that introduce another step to the process of obtaining the prescription from the pharmacy. Another modification that will improve adherence is to relax strict utilization review (UR) and prior authorization (PA) requirements for complex cases and concurrently allow provider-based teams to engage pharmacists from the PBM or local pharmacy to participate in care planning designed to improve adherence.

8. Ensure the medication is administered as ordered.

Behavioral reminders, blister packs, daily pillboxes and linkage of scheduled medication with other desired activities are some of the interventions that can remove some of the burden for patients, especially patients who have more than one prescription and whose regimen requires dosing more than once per day — a situation in which non-adherence is most frequent.¹⁰⁰

9. Share information to ensure all participants are aware of the extent to which adherence is occurring.

Over the past few decades, advances in health care analytics have provided exponentially growing data and information on many aspects of clinical practice. MCOs can be active facilitators of data-sharing among their network providers to identify gaps in prescriptions and profile patients' overly complex regimens. MCOs and their subcontractors, whether they are PBMs or behavioral health "carve outs," have access to claims and pharmacy data for all providers and can identify patterns of prescription utilization and non-utilization that can help providers design interventions to address non-adherence.

PBMs are another resource for harnessing the wealth of data on prescribing patterns. Solutions offered by PBMs and payers include aggregated reports of medication non-adherence to the provider as identified by pharmacy claims, yielding another important data point for the provider to assess adherence and discuss how to improve it with the patient. Improved data-sharing between the pharmacy that fills the prescription and the provider who wrote it will ensure that the provider has the most up-to-date information about the patient.

When there are multiple providers prescribing different medications — as is the norm with high-cost, high-risk, complex cases — they all need up-to-date information on prescriptions. A solution is access to a table that lists all prescribed medications for the patient, including a field notifying the provider that prescriptions have been filled — ideally with electronic communication across record systems. This feature will allow providers to assess the patient more accurately, reduce duplication, identify potential contraindications and develop timely interventions to address the patient's needs more exactly.

Finally, there is no greater opportunity to improve adherence and reduce medication errors than in transitions of care. Managed care organizations (MCOs), insurers and PBMs all have a key role in designing an effective solution to ensure that prescriptions are reconciled and to inform the community prescriber of any changes during inpatient admission and discharge.

Further Considerations

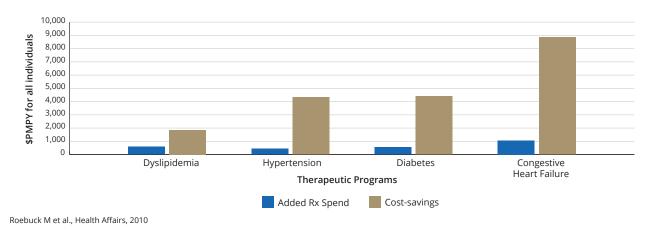
1. Identify champions for medication adherence initiatives at each level of the health care delivery system.

All members of the Expert Panel were strong advocates of a full range of program models designed to improve adherence. Any initiative to address non-adherence will require strong leadership at all levels to engage stakeholders, staff and constituencies. A review of these best-practice examples from the published literature clearly indicates that sustained gains will require **champions within the respective organizations to spearhead initiatives to improve adherence.** Examples of champions include payers, state regulators and state mental health authorities (see https://www1.nyc.gov/site/doh/providers/resources/public-health-action-kits-medication-adherence.page and https://www1.nyc.gov/assets/doh/downloads/pdf/csi/csi-map-pocket-folder. pdf), provider associations and consumer and family organizations such as the National Consumers League. 101, 102, 103, 104

2. Financing adherence initiatives attached to outcomes.

Many current initiatives from CMS and insurers include clear measures of accountability related to managing the total cost of care. There is ample evidence that increased adherence reduces total cost of care for many chronic conditions. ^{105, 106, 107, 108} The timing is right for a broader application of solutions tied to reduced total cost of care and establishment of quality indicators, including state- and county-initiated medication adherence initiatives to achieve savings at the local, county and state levels.

Cost-Savings from Adherence



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It also would be worthwhile to reimburse peers in mental health programs, including "bridgers" who are involved before discharge and stay involved until the person is engaged with community providers, and recovery coaches in MAT programs, especially those assisting patients from a variety of backgrounds.

With their wealth of information on patients who are receiving multiple prescriptions and overly complicated medication regimens, payers and PBMs are uniquely positioned to establish simplified regimens and a reduction in ineffective and contraindicated prescriptions for high-risk, complex and high-cost populations. The commitment of resources can lead to streamlining the authorization process, including reduction or elimination of the requirements of step therapy.

As noted earlier, payers and PBMs engaged in improved management of care (and not operating solely as administrative service organizations) can support an expanded role for pharmacists on treatment teams by adding reimbursement codes for their direct care and care-coordination activities.

Payers can establish standards for care management programs at the payer and provider levels to encourage simplification of medication regimens. They also can include standards of care that require the completion of a risk assessment that addresses adherence, as well as develop a standardized adherence protocol for patients that includes techniques of MI. A related solution is for payers and PBMs to identify opportunities to replicate MTM for high-risk, high-cost, low adherent populations and programs.

Finally, payers should ensure that there is a robust provider network for members to access prescribers of clozapine and LAMs for their covered populations, thus offering a broad range of options to address non-adherence.

3. Workforce.

Training and continuing education are integral parts of health care delivery for all practicing clinicians. The solutions to poor adherence involve five competencies for addressing the problems cited earlier. The following competencies should feature in the educational and training curricula of all mental health professionals. Particular emphasis should be placed on training psychiatric physicians in the use and administration of LAMs and clozapine.

- a. Assessing risk of non-adherence. While agencies can insert the form, providers and care management teams must interpret the data and determine how to work with the patient to maintain trust and identify the specific solution for each patient.
- b. The literature has examples of the benefits of MI and its success in improving adherence. Training and supervision toward competency is crucial for providers and their team members.
- c. Training and coaching on shared decision-making provides a strong foundation for engaging patients from a strength-based, recovery-oriented perspective. Interventions, including prescriptions, are much more likely to be effective when the patient and family have participated actively in the treatment plan.¹⁰⁹
- d. Building competencies for a team approach to complex, high-risk patients, including patients with low rates of adherence, will expand the range of interventions available from the provider. When teams include peers, people in recovery from substance use disorder and pharmacists, there is a much greater chance of matching the appropriate intervention to the patient's individual needs which increases adherence. The team members need to have cross-training on the language and clinical perspective of other team members to build competencies among disciplines; pharmacists must understand the recovery orientation of peer counselors and providers and prescribers must be skilled in working with pharmacists.
- e. Strengthening competencies of staff to meet the unique needs of patients from varying backgrounds.

4. MAT for substance use disorders.

The organization of services for treatment with medication for people with substance use disorder differs significantly from programs and services for people with mental health disorders. The experience with medications such as buprenorphine, naltrexone and Vivitrol is much more recent and there is little research based on random populations and validated results. The solutions that fall more under "best" or "promising" practices need to be vetted and validated through further research.

The provider should closely monitor patients' adherence with abstinence from other medications and adherence to prescribed medications through regular and random drug screens. A gradual reduction in requirements and office visits will take place only after the patient has demonstrated adherence to the medication and abstinence from opioids. Another best practice is to require patients to participate in concomitant therapy, such as group counseling, individual counseling, psychosocial treatment and active rehabilitation. These supports will help maintain adherence and prevent relapses into opioid, alcohol or other drug use that are often the cause of the non-adherence.

Perhaps the most promising practice on the largest scale has been implemented by a large insurer in several states in New England: the use of recovery coaches in concert with the prescriber working with patients in their community setting. Early indications are that recovery coaches are associated with greater increases in retention than programs providing MAT according to an established model.

Another solution that holds promise is the use of long-acting buprenorphine through a monthly injection or a sixmonth implant. But there are no definitive results to date.

5. Technology.

The interface between technology and health is ever-expanding and the effort to improve medication adherence through compatible devices, pill implants, reminder alarms and other apps is no exception. An increasing number of apps — applications generally downloaded to a mobile device — are being developed to remind people to take medication or monitor symptoms. The degree of sophistication has extended to implanting sensors in medications; these report that the medication was actually ingested, the best verification of adherence. The first example of this was the combination of the MyCite sensor with Abilify that was reported in The New York Times in November 2017. While this product is a significant milestone, its actual clinical value — much less its cost-effectiveness — is unknown.

Other approaches that leverage technology to enhance the effectiveness of medications include cloud-based treatment regimens that integrate medications prescribed by different providers and administered by different pharmacies or benefit organizations (http://www.rxadvance.com).

The Expert Panel conducted a survey of these apps and technology enhancements and, while many sounded promising, none has yet established a track record of effectiveness through randomly controlled studies. In fact, a major shortcoming is lack of stickiness: neither patients nor prescribers persist in using apps for long periods after the novelty has worn off. The Expert Panel is open to innovations in the marketplace and there is growing evidence that patients' facility with smartphones can be a resource for treatment and recovery. However, we want to ensure that there is adequate review of effectiveness and preservation of patient privacy and consent in the adoption of any technology. The Expert Panel suggests that stakeholders interested in any of the new technologies apply them with established measures of success in the settings where patients are treated and that they commit to an objective evaluation of the intervention in these practice-based settings.

Recommendations/Call to Action

This section lists specific, concrete and actionable recommendations to improve medication adherence. The recommendations are specific to four distinct stakeholder groups:

- Government
- Payers
- · Behavioral health care treatment organizations and their state and national trade organizations
- · Consumers, families and their advocacy organizations

The recommendations are designed to present a wide range of options so any individual stakeholder can choose what is most immediately feasible.

Recommendations for All Stakeholders

Recent literature reviews of interventions to improve medication adherence report that single interventions such as patient education or technology approaches to reminding people to take their medication are not effective. 111, 112 Implementation of multiple interventions by multiple stakeholders, applied over time and with consistent follow-through, will be necessary to make substantial improvements on medication adherence. Closer working partnerships will need to be developed among payers, health care treatment providers and pharmacies to put into place the information exchange connectivity and payment methodologies required to support implementation of many of the following recommendations.

Government involvement and support will be needed to make the necessary regulatory changes.

It is critical all stakeholders understand that improving medication adherence is arguably the greatest opportunity to improve treatment outcomes and achieve cost savings in our health care system.

1. Identify champions for medication adherence initiatives at each level of the health care delivery system.

Each of the stakeholder groups needs to put forward initiatives and identify a champion, a member in a leadership position who will be charged with carrying through on the interventions. It is the responsibility of the leadership of these organizations to identify and promote their champions.

SAMHSA and CMS can select the department, program or policy area where medication adherence fits most closely and identify the managers who oversee the related initiatives as point persons visible to other stakeholders.

Professional and provider associations can draw from established committees or programs related to clinical practice that are willing to take on medication adherence as a priority project.

Payers and PBMs that manage patients and services, as well as PBMs that operate as administrative services organizations (ASOs) only, should identify parties responsible for improved data exchange, medication reconciliation and quality outcomes that have experience in tracking rates of adherence.

Advocacy organizations can identify national, state and local groups that can lend the consumer and family voice that is integral to effective solutions. The peer workforce can advocate for SDM to address member-centered goal attainment and, once agreement is reached on medication as a goal, the role of medications in recovery.

The National Council Medical Director Institute will be a clearinghouse for activities in each of the stakeholder groups to promote information sharing and collaboration in the identification of champions within each group.

The Expert Panel offers several strategies to help these stakeholders identify a champion in their midst:

- Add the problem of non-adherence to the agenda of organizations and trade associations that are undertaking strategic planning.
- Tap people with best practice experience, research into the topic or broad-based knowledge to provide background information above and beyond this paper to members and build a case for adopting medication adherence as a key strategic goal.
- Name champions from fiscal management, program management and legal across all benefit/service categories. This will promote assessment of a wide range of recommendations and their possible ramifications.
- Develop grassroots support for the goal at the membership, board and executive committee levels within each stakeholder group.
- Advocate for resources to craft solutions through committees, appropriate staffing and outreach to other stakeholder groups.

2. Improve health and mental health literacy across all.

The importance of improved health literacy cannot be underestimated. Health literacy in these settings is not a blanket exhortation to "follow the doctor's orders." Rather, health literacy approaches communities individually and seeks to align best practice approaches to health within the individual community based on customs, access to care over time, unique beliefs of the etiology of mental health problems and substance use disorders, and strategies to engage these groups based on their community's practices.

Health literacy also includes research on the responsiveness of different groups to medications, prevalence of illnesses within certain groups and the variations of the notions of recovery, health and rehabilitation that exist in different communities.

Each of the stakeholder groups can renew efforts to harness the expanded resources of social media to craft campaigns to improve health literacy that are customized to specific populations.

3. Establish core competencies for motivational interviewing and shared decision-making as foundations for patient engagement and treatment.

The Expert Panel believes that it is important that any initiatives on medication adherence embrace two key underlying principles of recovery: patients must be actively engaged in defining their treatment and recovery goals and the steps to engagement necessarily include mastering the skills of motivational interviewing and embracing the principles of shared decision-making.

Government, payers, provider trade groups and advocacy organizations can be unified in ensuring that these principles are applied to their programs, providers and patient populations. Each stakeholder group can promote SDM and MI as clear and concise competencies related to patient engagement that are measurable at the individual, organizational and population level.

Recommendations for Government

1. Attach financing adherence initiatives to outcomes.

CMS continues to push for policy initiatives for Medicare and Medicaid populations that shift the emphasis from fee-for-service reimbursements to payments based on patient outcomes. Most of these efforts emphasize medication reconciliation around transitions of care. The Expert Panel urges CMS to include continued medication adherence after the transitions of care as another key outcome measure. Improvement of medication adherence will maintain the gains of emergency and inpatient treatment and increase the chances of recovery from the mental health and substance use disorders.

- Within Medicare the current library performance indicators available for the merit improvement performance systems (MIPS) do not measure performance adequately in the area of medication adherence, particularly for psychotropic medications. CMS should develop additional MIPS performance indicators related to medication adherence.
- The current guidance for meeting advancing care information requirements in MIPS does not adequately incentivize care information requirements that would improve medication adherence. The information sharing recommendations that follow should serve to meet advancing care information requirements under MIPS.
- The current guidance for meeting the quality improvement requirements in MIPS should be revised to encourage medication adherence as a preferred focus for a quality improvement project required under MIPS.
- The Medicare Inpatient Psychiatric Facility Quality Reporting Program includes several important measures
 that can enhance adherence. These include ensuring that transition records are received by the next level
 of care and rates of the discharged patient getting a follow-up visit seven and 30 days after psychiatric
 hospitalization. But, unfortunately, this program is only a reporting program with no incentive for the reporting
 hospitals to improve. We urge Congress to make this program a bonus/penalty program to further incentivize
 improvement.
- Within the Medicare Advantage Program, the Quality Improvement Project (QIP) and Chronic Care
 Improvement Program (CCIP) Resource Document 2017/2018 contains nothing specific to medication
 adherence. CMS should provide specific guidance incentivizing Medicare Advantage Plans to implement QIPs
 and CCIPs that focus on improving medication adherence consistent with the detailed recommendations of
 this report.

2. Regulatory recommendations.

Congress recognized the importance of access to mental health medications when it created the Medicare Part D prescription drug benefit. It recognized six classes of clinical concern and instructed plans to provide all or substantially all drugs in these classes — including antipsychotic medications and antidepressants. We urge Congress to extend this policy to include medications for the treatment of substance use disorders in Medicare Part D.

CMS can improve adherence by standardizing preferred drug lists and prior authorization requirements across Medicare Part D providers or at least incentivizing them to minimize changes in these areas. CMS should require that patients previously taking medication with good adherence be permitted to continue that medication indefinitely (the medication should be grandfathered in) if there are subsequent changes to its place on a preferred drug list or to its prior authorization requirements. Application of a step-therapy algorithm should never require patients to discontinue medications they are adherent to and doing well on. The Food and Drug Administration (FDA) can minimize confusion for patients by requiring similar size, shape, color and form for generic medications

with multiple manufacturers. Changing the appearance of the pill confuses patients and increases the likelihood of non-adherence.

State Medicaid agencies can require that their managed care and pharmacy benefit contractors use the same formulary statewide, along with the same preferred drug list and prior authorization requirements and related paperwork.

State Medicaid agencies should require that their managed-care and pharmacy-benefit contractors implement, on an annual basis, at least one CCIP that is focused on medication adherence.

3. Share information.

The Expert Panel recognizes that, while CMS has two large and important data sets — one for Medicare patients and another for Medicaid patients — that can be accessed and shared with providers to identify adherent and non-adherent patients and patient populations, there are several real barriers to making the sharing of these data sets universal. The following recommended actions for CMS leverage several mechanisms to accomplish the goal of increased adherence.

CMS can work to facilitate transmission of Medicare Part D pharmacy claims for Medicaid/Medicare dual eligibles to the patient's state Medicaid agency in real-time through the same mechanisms (TrOOP and Switch) used to adjudicate the claim. This transmission will allow the state Medicaid agencies to use the information to improve medication adherence before adverse clinical outcomes occur.

CMS should undertake development of standards for pharmacies to routinely and automatically transmit fill transactions to the source of the prescription that they are filling and develop corresponding standards for electronic medical records to receive and record the fill transactions. When prescribers know if a prescription has or has not been filled, they can be much more effective in improving medication adherence.

CMS should also require e-prescribing for all Medicare and Medicaid patients nationwide. Currently there only four states where e-prescribing is required: Maine, Minnesota, New York and Connecticut, though many others are in different stages of regulatory or legislative requirements for greater use or broader encouragement on adoption of the practice.¹¹³

CMS and SAMHSA should provide funding for behavioral health providers to adopt electronic medical records and e-prescribing and to connect with health information exchanges consistent with funding previously provided to other types of health care providers. With such capacity, behavioral health providers will be better positioned to reduce duplication of medications, unintended adverse side-effects and complicated regimens for their patients — all factors related to non-adherence.

SAMHSA should provide funding for training and implementation of shared decision-making and motivational interviewing that includes improving medication adherence.

CMS should encourage use of SDM and MI by issuing guidance that both techniques fall within the definition of patient counseling under CPT (American Medical Association's Current Procedural Terminology) Evaluation and Management coding guidelines. These guidelines state that when more than 50 percent of a provider's time is spent on patient counseling, the coding level is determined by time spent and not by complexity of the evaluation and medical decision-making. Thus, billing a higher-level evaluation and management code is permitted when more than 50 percent of the time is spent in SDM and MI to address medication adherence.

4. Expand roles for pharmacists: Allow codes for pharmacist participation on clinical teams and establish standards for consultation with pharmacists.

Some of the best practice interventions using MI and team-based approaches to care management include participation of pharmacists on clinical teams at both the provider and payer level. The Expert Panel recommends that CMS include a code for pharmacists to be reimbursed for consulting with providers and participating on clinical teams at the provider level.

State policymakers should expand the scope of practice for pharmacists to allow them to administer injections of medications used for mental illness and substance use disorders.

5. Monitor expanded technologies and apps.

CMS, SAMHSA and other federal agencies must be the gatekeepers to a well-established body of research on the effectiveness of these technologies.

The Expert Panel recommends that CMS and SAMHSA monitor the development of these apps and ensure that adequate testing of their effectiveness is conducted before large-scale promotion to these populations, especially populations with chronic and severe behavioral health conditions.

Recommendations for Payers

1. Management of care.

The Expert Panel recommends that payers assess risk of non-adherence based on the complexity of medication regimens (frequency of dosing, risk of side-effects, caveats of administration) and patients' history with adherence and share their findings with providers. Payers can customize the risk assessments and in-depth review for certain populations based on diagnosis, treatment history and changes in medications. Payers can track the outcomes of these efforts in improving adherence, reducing use of more restrictive services and promoting best-practice providers.

2. Modify incentives for adherence and reduced total cost of care.

Payers need to modify incentives to promote the value of medication adherence from the perspective of total cost of care. Often, pharmacy benefit plans are completely misaligned with medication management interventions that can impact overall adherence. Evaluation of the return on investment (ROI) for implementing medication adherence improvements should include changes in utilization and expenditure across the full range of benefits/ services including hospital, outpatient and all other covered services, as well as pharmacy costs. The ROI for implementing medication adherence improvements for one diagnosis should include changes in utilization and costs for all conditions and diagnoses.

Specific recommendations for aligning incentives include:

- Establish practice-based models to evaluate improvements in adherence and cost-savings with evolving models of value-based payments including Accountable Care Organizations for the Medicare, commercial and Medicaid populations.
- Establish pay-for-performance (P4P) initiatives that specifically address improved medication adherence
 performance measures. Both patient and provider should benefit from incentives and utilize evidence-based
 and best-practices processes such as SDM and MI.

- · Align medication adherence programs with CMS and National Business Coalition on Health.
- Review impact of reducing or eliminating co-pay to improve adherence.

Payers can also fund initiatives that address the social and environmental factors that affect health, which that are obstacles to medication adherence and long-standing barriers to health care, including medications, for more vulnerable populations.

Payers can remove consumer restrictions and disincentives that limit access to programs that improve medication adherence by reimbursing for adherence packaging, face-to-face engagement with the pharmacist, clozapine monitoring and medication synchronization.

Payers should reconsider practice changes that require members with complex medications to switch to 90-day mail order without regard to impact to adherence and medication monitoring.

Payers should cover MTM services and injections by pharmacists.

Payers should cover synchronization services by pharmacists where all medications are filled on the same day of the month.

Payers should cover laboratory testing (blood and urine) for monitoring medication adherence.

Pharmacy dispensing fees should incentivize bubble pack dispensing for patients on stable medication regimens. Payers should also incentivize pill-minder programs for patients with complicated regimens.

Medication adherence is unlikely when patients do not have adequate access to and time with their prescribing providers for discussion to build the understanding and trust necessary for good medication adherence. Payers can increase the amount of time that prescribing providers must work on medication adherence by setting provider rates that are adequate to cover the actual cost of the care. Additionally, they can minimize prior authorization requirements that the provider spend time away from the patient.

Payers should encourage use of SDM and MI by issuing guidance that both techniques fall within the definition of patient counseling under CPT Evaluation and Management coding guidelines if more than 50 percent of the interaction is devoted to patient counseling (in this case SDM and MI related to medication adherence). In such a case, the coding level is determined by time and not by complexity of the evaluation and medical decision-making. This will allow billing a higher-level evaluation and management code when more than 50 percent of the time is spent in SDM and MI to address medication adherence.

3. Share information.

The Expert Panel recommends that both MCOs and PBMs harness data analytics to assist providers in identifying gaps in adherence among individuals by provider and population. These payers should implement audit and feedback programs that analyze claims for patterns of non-adherence and provide that information to the providers prescribing for these patients, along with recommendations for improving their medication regimen. Audit and feedback programs are appreciated by providers and proven effective in improving adherence and outcomes.

Payers can develop flags for high-risk diagnoses and populations that offer the best opportunities to improve adherence. Payers can identify payer-provider collaborations and replicate the models across their provider network. MCOs and PBMs can work to address the challenges of integrating pharmacy claims data from PBMs with clinical services data from MCOs

Payers should incentivize improved information sharing on medication reconciliation at the time of inpatient admission and discharge as a prospective solution for improved adherence.

MCOs and PBMs should report on records of individual pharmacy claims of medications filled and make them available to the prescribing providers through a secure data portal. When prescribers know if a prescription has or has not been filled, they can be much more effective in improving medication adherence.

Pricing and out-of-pocket costs should be made more transparent by all insurance companies up front, allowing providers and patients ready access to the cost of various treatments. (See the Medicaid website of the state of Ohio, which lists every medication and possible co-pays at https://druglookup.ohgov.changehealthcare.com/DrugSearch.)¹¹⁴ Providers must ensure that they understand patient preferences in relation to medication out-of-pocket costs and they must assure patients that they are considering these costs and minimizing them as much as possible.

4. Expand roles for pharmacists and PBMs.

The Expert Panel recommends that payers assign pharmacists to behavioral health populations with low rates of adherence with the goal of engaging the patient and supporting the provider in a coordinated effort to improve adherence. Payers can allocate pharmacists to focus on the highest-risk populations for the best return on investment of resources. The Expert Panel suggests that payers encourage collaboration between local pharmacists and behavioral health providers as an additional support to high-risk patients.

Pharmacists can contribute to improved adherence with improved information sharing through software that aligns pharmacies with providers for real-time information sharing. A practical recommendation is for payers to install pharmacy dispensing software systems to enable a pharmacy to "push" or "ping" back to the provider within the e-prescribing system when a prescription is filled. A necessary component is the capacity of the provider's EMR to insert the pharmacist's reply on medication filled by the patient directly into the EMR. This timely information will help the provider assess the patient's adherence accurately.

5. Encourage utilization of long-acting injectable medication.

All parties can reduce the stigma of LAMs by adopting the term "long-acting medications (LAM) administered by injection."

All medications for which a LAM formulation is available should be accessible on the formulary without prior authorization or higher co-pay and covered under both the pharmacy and medical benefit. Restricting LAM antipsychotic and MAT medications to a medical benefit restricts access, including for onsite clinic pharmacies.

Pharmacy claims for medications for which a LAM formulation is available should be analyzed by payers to identify people with patterns suggesting medication non-adherence to the oral formulation. The payer should recommend to both the prescriber and the patient that an LAM formulation be considered.

Payers must ensure appropriate network access to antipsychotic medications and medications for treatment of addiction, including LAMs. Payers should consider limiting mail-order specialty pharmacies for patients with a track record of poor medication adherence. Mail-order dispensing can result in delays in administration, which may lead to non-adherence and risk of hospitalization. But regular interactions with a local pharmacist can substantially improve adherence, especially when utilizing MTM.

"Remembering to take my pills at lunchtime is the worst.

I live a very active life and I miss taking them. That's why I love my shot.

I never miss it or forget it. I think they're a benefit."

— Consumer Responding to an Agency Survey

6. Support the use of clozapine.

Clozapine has been proven to have certain efficacy advantages (antipsychotic properties, relapse prevention, and reduction of suicide, violence and substance use) in specific patient populations, yet it is greatly underutilized. While clozapine's side-effect profile clearly restricts the range of its use, it has distinct advantages that are not being exploited. Providers need to develop the requisite knowledge, skill and comfort level for using clozapine and for explaining its advantages and disadvantages to patients and families. System supports are needed to overcome the obstacles posed by lab monitoring and the regular approval process from prescription to distribution, including the need for frequent lab and pharmacy visits. This is especially imperative for a population that is often challenged by bio-psychosocial factors.

7. Avoid non-adherence resulting from formulary changes.

Payers should avoid or at least minimize changes to preferred drug lists and prior authorization requirements. Patients previously taking medication with good adherence should be allowed to continue it indefinitely (the medication should be grandfathered in) if there are subsequent changes to its place on a preferred drug list or its prior authorization requirements. An additional recommendation is to align the inpatient formulary with the insurer's outpatient formulary and to promote prior authorization for the outpatient medication coverage during the inpatient admission and establishing a protocol for direct contact between the inpatient and outpatient pharmacists.

Recommendations for Health Care Providers

1. Improve communication between provider and patient.

Providers and their national and state associations should commit to improved communication for all their members and codify the solutions in their operating principles and ongoing strategies to improve care. Individual members can commit to a course of improved communication and establish provider-based continuous quality improvement activities on increased medication adherence. The Expert Panel suggests that trade associations offer technical assistance based on the research contained in this paper, as well as access to the thought leaders on these topics within their associations. All staff with direct patient contact should receive training in MI and SDM.

"Finding the right medication that helps is irritating. I've been through almost all of them and they don't work yet. I quit every now and then. It makes me more depressed and kind of give up hope that nothing will work."

- Frustrated Patient

2. Based on findings from the risk assessment, match provider interventions and medication regimen to patient's individual needs.

Providers choose and use a standardized medication adherence risk assessment.

Providers or other team members should adopt guidelines for assessing medication adherence during initial interviews and update them at periodic reviews or following hospitalization or psychiatric crisis in the community. The guidelines for the adherence review should include collecting information on where patients store their medications as part of the step-by-step process of taking their medications.

"Medication adherence isn't always easy. One medication caused me to gain 100 pounds in six months. Others caused me to be very sleepy during the day, which interfered with my ability to work. But I know now that by not giving up until finding the right medication, along with using a lot of coping skills, I've been able to live in recovery for the last 10 years. So, I'm glad that I stuck with the medication."

— Consumer

Providers should systematically track the extent of risk assessments, adherence reviews and in-clinic medication reconciliations through EMR audits and benchmarking.

Therapists, case managers, peer-support specialists, addiction counselors and the full array of behavioral health organization staff should be trained in medication adherence improvement and actively promote it during their interactions with patients. Medication adherence improvement efforts should not be limited to physicians, nurses and pharmacists. Full team involvement will be maximally attained when the goals are articulated during SDM and can be found in the treatment plan.

One common tool used in in-care planning with patients in other non-behavioral health settings is the advance directive. This practice is a good example of a SDM process that has been advocated in other sections. The Expert Panel believes that the advance directive can be introduced in the care-planning between provider and patient as an element of SDM and will enhance the patient's commitment to adherence.

The Expert Panel urges state and national provider and professional associations to emphasize the importance of a risk assessment on medication adherence as part of the diagnostic formulation and patient history and address any risks for non-adherence in the patient's treatment plan. Professional and provider associations can add these components to existing practice guidelines. They can also develop clearinghouses and provide technical assistance for the many practical solutions to improved medication adherence that are listed in the Solutions section.

Annual meetings can adopt medication adherence as a key theme.

Provider associations can help members align their practices more closely with standards of context awareness for patients from various backgrounds who have a range of beliefs about medication and health care overall. This recommendation includes hiring staff from the same background as the patients.

3. Simplify medication regimens.

At least annually, each patient's medication regimen should be reviewed for opportunities to reduce the number of medications and the number of times a day that medication must be taken. Behavioral health organizations should benchmark the simplification of medication regimen by individual provider. This may be most conveniently done during a specific medication reconciliation visit.

During the annual review, providers should have patients bring all their medications to the clinic so the provider can conduct a reconciliation and review of adherence through pill counts. This will also help identify ways to simplify regimens and allow patients to dispose of medications that are no longer being taken.

4. Medication reconciliation after discharge.

Providers can align their EMRs to the payers for timely exchange of medication information at the time of discharge of their patients from inpatient and rehabilitation settings. The receiving pharmacy can be a resource to the provider for the reconciliation activities.

As soon as possible after every hospital discharge — including those involving people treated for mental illness and addictions — patients should have a clinic or home visit for the purpose of medication reconciliation. The results of the reconciliation should be shared with all dispensing pharmacies and other providers. Medication reconciliation should also occur as soon as possible following release from jail or prison.

Providers can also deploy "bridgers" as separate staff or assign peer counselors to this role as a support for the information sharing needed to improve adherence and gather accurate information on medications.

"Through our work with one primary pharmacy in our community, we have worked to fill either medication boxes or bubble packs for over 250 individuals with serious mental illnesses which we distribute to clients on a weekly basis. This system along with our community support program's efforts, has resulted in dramatic decreases in emergency room visits and psychiatric admissions for this population."

— Large Community Mental Health Center in the Midwest

5. Maximize the use of long-acting medications.

Providers should be able to administer LAMs in their clinics and have cooperative agreements with local pharmacies that administer LAMs onsite.

Providers should receive training including MI and SDM on presenting the LAM treatment opportunity to patients most effectively. Behavioral health organizations should benchmark the rate of LAM utilization by their individual providers.

Providers must commit to ongoing training of staff on effective methods of injections to minimize discomfort to patients.

Tips on how to talk with patients about LAMs

The Center for Practice Innovations, led by Lisa Dixon, has some materials that may be helpful:

http://practiceinnovations.org/Consumers/Medication-and-Medication-Side-Effects

and

http://practiceinnovations.org/Consumers/Motivational-Interviewing

6. Maximize the use of bubble pack dispensing, pillboxes and other state-of-the-art tools to aid in adherence.

Providers should preferentially refer to and develop cooperative agreements with pharmacies that offer bubble pack dispensing, pillboxes and other state-of-the art tools that promote medication adherence. Providers should routinely request bubble pack dispensing from pharmacies. When bubble pack dispensing is not available or regimens are less stable, providers can lobby payers to provide patients with weekly or bi-weekly pill planner boxes. There are a growing number of sophisticated tools to choose from. Providers and payers can convene with pharmacy manufacturers to make the tools more available. Case studies have shown success in numerous communities with targeted interventions for patients facing complicated regimens.

"Remembering to take my meds is the hardest part. The packaging really helps.

I like the bubbles and can easily tell if I've missed a dose."

— From a Consumer Survey at an Agency

7. Utilize laboratory testing to monitor medication adherence.

Medication adherence should be periodically monitored by laboratory testing. Urine testing is preferred for patient comfort and convenience. Behavioral health provider organizations should have either the ability to collect specimens or work with a conveniently located lab that offers seamless insurance coverage and ease of communication with the provider.

8. Utilize in-house pharmacies.

Providers should utilize in-house pharmacies when possible to improve patient convenience and provider/ pharmacist communication regarding adherence and simplification of medication regimens. Pharmacists embedded in behavioral health organizations should have access to the EMR. In-house pharmacies can also assist in clinical pharmacy engagement with treatment teams and patients.

9. Effectiveness of apps remains unproven.

There are a growing number of apps being developed and promoted to monitor and improve medication adherence. They include time reminders for complex regimens, reinforcement strategies, bidirectional communication with providers and pharmacists. To date, there is not sufficient research and evaluation of their outcomes to recommend broad systematic adoption. They remain an exciting possibility for further improvement.

10. Workforce (through associations and training entities).

Another recommendation from the Expert Panel is that national and state professional and provider associations emphasize competencies in their workforce in SDM, MI and addressing variety in customs, beliefs and backgrounds of their patient population. Providers can expand membership on clinical teams to include peers with lived experience and recovery coaches in MAT programs. The Expert Panel recommends that these associations track results of these staffing models and report on results related to key outcomes, including improved scores on medication reconciliation and medication adherence.

All behavioral health organization staff — not just psychiatric providers — should receive training in risk factors for medication non-adherence, the impact of medication non-adherence and methods of improving medication non-adherence.

Such efforts can be supported through ongoing training programs in risk assessment, MI and positive behavioral communication.

11. MAT solutions.

The risk assessment and workforce development solutions apply to MAT programs as well. The use of recovery coaches is emerging as a promising practice among MAT providers. National and state trade associations can help members identify adherence as a problem to be measured and orient their members toward solutions and resources.

12. Effectiveness of genetic testing remains unproven.

Recently batteries of genetic testing regarding various aspects of medication metabolism variations in receptor structure have become available. There is not sufficient evidence that it improves medication adherence to recommend this as a strategy.

Recommendation for Advocates

1. Improve communication between provider and patient.

The Expert Panel believes that advocates play an important role in solving the problem of poor communication between provider and patient. The Expert Panel recommends that advocates have a seat at the table as providers and provider associations develop these solutions, especially around a provider's tendency to overestimate a patient's adherence — a phenomenon often accompanied by the patient's tendency to overreport adherence. The advocate's unique voice can help providers place medication adherence within the context of recovery and affirm that medication adherence is not an end in itself within the therapeutic alliance.

Advocates can lobby for a broader application of SDM in the provider-patient relationship so that the patient can articulate the role of medication in the goals of recovery.

2. Based on the risk assessment, match provider interventions and medication regimens to patients' individual needs.

The Expert Panel suggests that advocates also lobby providers to expand the types of practical resources available to patients and their families to address high-risk members. They can encourage providers to adopt a medication adherence quality improvement initiative and participate in the design of solutions and evaluation of successes.

3. Workforce.

Advocates should also lobby for expanded use of recovery coaches, peer supports and staff that represent the background of the population the provider serves. These varied voices will ensure responsiveness from the providers and their participation will ensure effective solutions.

4. Underscore health and mental health literacy for special populations.

The Expert Panel believes that advocates should have a key role in effective messaging on health literacy, especially to varied populations that have unmet needs. The Institute recommends that advocates help to formulate messaging to these subgroups, which require unique approaches to engage them in the discussion. The Expert Panel believes that advocates can be an integral part of the solution and offer a unique perspective to policymakers, public health professionals and providers.

Concluding Statement

We hope that this report has persuaded the reader to be deeply concerned that non-adherence to prescribe medications is:

- Extremely common.
- Frequently undiagnosed and unaddressed.
- A major cause of poor treatment outcomes and increased costs.

We hope that the reader will be moved to action knowing that:

- Multiple options are available for improving medication adherence.
- Multiple actions are needed to improve medication adherence.
- Multiple stakeholders must take action if improvement is to occur.

"Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments."

- World Health Organization

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Expert Panel

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Resources

Case Study: An Analysis of Medication Adherence at Family & Children's Services

Nikki Harrop, MA, LPC Family & Children's Services, Tulsa, OK, 2017

Abstract: Patient adherence to a medication regimen is central to positive recovery outcomes. Poor medication adherence contributes to treatment failures, increased hospitalizations, and puts patients at increased risk for homelessness, incarceration, and violence (Lee, 2013). Medication adherence is a multidimensional issue that impacts the recovery process for people with severe mental illness. Through the development of an organizational culture that is focused on medication adherence, all levels of staff can assess for and identify barriers to adherence every service. By using these tools, consumers receive consistent, person-centered treatment which addresses barriers as they're reported. As barriers are addressed through simple, targeted solutions, adherence increases for the Family & Children's Services client.

Background

Family & Children's Services offers comprehensive mental health care services to Tulsans across the life-span spectrum, including over 100,000 people each year. Most clients served by the agency are surrounded by and at high risk for poverty, homelessness, and chronic illness. A majority of adherence related efforts prior to May 2017 were focused within programs that serve adult populations. An exception to this would be the in-house pharmacy, which serves clients receiving medication from Adult and Child Psychiatry Clinics. At every medication pickup, clients are asked if there are questions or concerns related to their medications. The in-house pharmacy also generated adherence rates automatically within their WinRx software. Those rates were based on Medication Possession Ratio (MPR). More specific adherence efforts related to the adult services include verbal screening for adherence at all adult psychiatry provider appointments. Client populations with more intensive needs, such as those recently discharging from the hospital under a court commitment for outpatient treatment, had Transitional Care case managers monitoring medication pickup thru the electronic pharmacy system. Family & Children's Services also has two Program of Assertive Community Treatment (PACT) teams which service clients with psychosis-based mental illness and struggle to engage in traditional outpatient treatment. The PACT teams manage daily and weekly medication deliveries in the community and monitor for adherence at each delivery.

While Family & Children's Services provided consistent attention to adherence in all adult psychiatry provider appointments, there were not cohesive or overarching adherence efforts between departments. Due to the agency's size, a lack of communication and coordination between generalized outpatient departments were reported as a consistent barrier for staff addressing the needs of consumers.

Initial Efforts

The initial approach to enhancing medication adherence at Family & Children's Services focused on four main goals; reducing barriers to psychiatry providers by providing rapid appointment availability, enhancing access to medications, adopting clinical tools to improve medication adherence, and focusing on increasing the number of clients on long acting injections (LAIs).

To increase access to psychiatry providers, Family & Children's Services increased the number of prescribers on staff, as well as increasing access to the same provider for continuity of care and relationship building. In addition to this, walk-in opportunities were added to the outpatient Medication Clinic and the 24-hour Crisis Care Center offered medication management to those seeking respite.

Family & Children's Services balanced increased access to psychiatry providers with increased access to medications. Through their in-house pharmacy, the Patient Assistance Program distributes \$20 million in free medications per year. Partnerships with Dispensary of Hope and community support/forgiveness for copays enabled the distribution of those medications.

The adult psychiatry team adopted clinical tools to improve medication adherence, including the SIMPLE method. SIMPLE focuses on simplifying regimens, enhancing the provider-patient relationship via knowledge sharing and communication, and evaluating adherence.

Promoting the use and acceptance of long-acting injectable (LAI) medication has been a cornerstone of adherence efforts at Family & Children's Services. From 2016 to 2017, the number of clients receiving injectable has increased dramatically. There are now close to 250 clients receiving a LAI as part of their medication management. Specially, over 90 clients are currently on a 3-month LAI and only one has been hospitalized for their mental illness since transitioning to it. Adult psychiatry providers operate from a philosophy that LAIs should be used as Family & Children's Services also works closely with community partners to stabilize clients long-term via LAI. This includes working with local judiciary to decrease inpatient stays by providing injections in urgent care recovery settings for committed outpatient clients. The agency also has partnered with a local inpatient facility to begin tracking the sustainability of starting clients on LAIs and transferring them to outpatient care.

Advanced Adherence Strategies

Family & Children's Services CEO, Gail Lapidus, wanted to push medication adherence in behavioral health to new levels of awareness in the agency. Much like trauma informed care permeates an agency's workplace culture to provide sensitive, responsive treatment at every level; she wanted the same for addressing the barriers to adherence. The main focus of the agency's medication adherence initiative is that medication adherence is everyone's responsibility. Previously, it had mainly been the responsibility of medical providers and specialty teams. Through the initiative, medication services are integrated and coordinated with psychosocial services to promote medication adherence and sustained recovery.

Following recommendations by the American College for Preventive Medicine (2011), Family & Children's Services began to look at integrating treatment to utilize and address all dimensions that affect adherence, including: social/economic, health care system, condition-related, therapy-related, and patient-related factors. To drive this new approach, a Medication Adherence Coordinator position was created within the agency. This position is responsible for improving client success through championing medication adherence support initiative and programs. With the support of medical and program leadership, the coordinator works collaboratively with all departments in the 16 Adult Severe Mental Illness Division. In May 2017, the position was filled and a comprehensive literature review was completed shortly thereafter.

Evaluating adherence within the client population began over the summer 2017 with three different tools. Firstly, the Intake Department began administering a Medication Adherence Questionnaire at all new patient intakes and 6-month treatment plan reviews. The Questionnaire is a 16 question composite of the Morisky-8 (MMAS-8) and Drug Attitude Inventory. Secondly, all department in the Adult Mental Health Division, except PAP and Pharmacy, screened for adherence at each visit. The screener consisted of a mandatory question embedded in the electronic health record's (EHR) individual service documentation. If a client identified as not taking medications as prescribed, a mandatory selection of adherence barriers was prompted. Lastly, an Adherence Barrier Questionnaire was administered to clients in the Medication Clinic to identify the frequency common barriers were contributing to missed doses in a given month. The questionnaire was adapted from an Adherence Barrier Questionnaire developed for HIV patients. The Medication Adherence Coordinator collaborated with the EHR team to pull data for review and analysis. Internal data from the in-house pharmacy software indicated MPR in the low 90th percentile. That data combined with staff observations of client non-adherence indicated that adherence issues laid more in the behaviors of clients following medication pickup.

As data began to be collected from clients, the Medication Adherence Coordinator began meeting with all teams within the Adult Mental Health Division to gather staff feedback and begin forming an interdisciplinary "Change Champion" team with representative from each department. Through collaborative work with the teams and the development of the "Change Champions" team, an organizational culture and framework regarding the importance of medication adherence began to grow. The expectation that everyone could help address barriers to adherence was gaining acceptance.

Through the growing organizational culture, common barriers found in adherence literature, and initial staff/client feedback; several pilots to address barriers were launched in late Summer 2017. The first and most successful pilot addressed the barrier of transportation, which was identified routinely as a common barrier within the Family & Children's Services population. The pilot ran for one month in Summer 2017 and addressed bus-based transportation amongst the most vulnerable populations, including the chronically homeless and those recently discharged from inpatient care. Participants were identified and enrolled by a combination of therapist, case managers, and recovery support specialists. There was a 66% increase in adherence among homeless clients and 64% increase in those involved in the Transitional Care Program. Adherence was measured using the previously mentioned MPR rates available in pharmacy software. Due to the success in these departments, the pilot was extended through October 2017.

In regards to bus tokens and transportation, the Change Champions team identified internally created boundaries by not providing bus tokens during the medication pickup process. Historically, bus tokens were available to clients receiving same-day services for all other programs, except PAP and Pharmacy. To eliminate the barrier and effectively manage resources, PAP began screening non-insured clients at every medication pickup for bus-based adherence issues. If a client indicates bus token would help improve adherence, a token is provided to them.

Internal data became available in early Fall 2017, indicating difficulty remembering and side effects were dominant reasons for non-adherence with the agency's population. This lead to the development of several new pilots. Single week pillboxes were given out by the Live Well team, involving initial set up with a nurse and evaluation of beliefs related to medication forgetfulness. The pilot is currently running for seven months, with monthly re-evaluation of use and beliefs by Live Well case managers. Additional reminder adherence tools will soon become available for the Adult Case Management department to distribute to clients who identify as non-adherent due to forgetfulness during face to face sessions and phone outreach.

To address the barrier of side effects, the Medication Adherence Coordinator collaborated with the Medical Director and Head Psychiatrist of the Crisis Care Center on creating Medication Appointment Prep Sheet. The prep sheet focuses on streamlining client concerns, expectations, and appropriate coping skills to use in conjunction with medications. In September/October 2017, the prep sheet was distributed to therapists in the Specialized Outpatient Services, recovery support specialists, and mental health technicians at the Crisis Care Center to complete with clients. The tool is designed to be a tool for self-advocacy and promote focused conversations on side effects/medication concerns.

The future of Family & Children's Services medication adherence initiative will begin to move into new phases over the winter of 2017. Additional parts of the initiative include an educational campaign targeted towards clients, enhancement of adherence related pharmacy services, and an incentive program for the most non-adherence portion of the client population.

Recommendations

Family & Children's Services is fortunate to have resources that allow for small and large scale adherence efforts. No matter the size of a provider, steps can be taken to addressing the barriers related to medication non-adherence. The first recommendation would be to develop an interdisciplinary Change Champion team. This team will act as the drivers for acknowledging the scope of the problem and creating buy-in that it is a problem everyone can help with. This team should begin by evaluating adherence within their own population, so efforts are tailored appropriately. Based on this data, the team can create targeted, simple approaches to common barriers found.

Providers should evaluate what role they play in creating barriers. By following the SIMPLE method for medication adherence, the provider can be aware of how multi-dimensional the topic truly is. The relationship between provider and client remains crucial to the issue of adherence. Promoting and implementing shared decision making into clinical process creates buy-in with both parties involved. The philosophy guiding medication adherence improvement should remain that this is everyone's responsibility. Medications work when everyone works together.

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Talking with Clients About Their Medication

Untreated psychiatric problems are a common cause for treatment failure in substance abuse treatment programs. Supporting clients with mental illness in continuing to take their psychiatric medications can significantly improve substance abuse treatment outcomes.

Getting Started.

Take 5–10 minutes every few sessions to go over these topics with your clients:

- Remind them that taking care of their mental health will help prevent relapse.
- Ask how their psychiatric medication is helpful.
- Acknowledge that taking a pill every day is a hassle.
- Acknowledge that everybody on medication misses taking it sometimes.
- Ask if they felt or acted different on days when they missed their medication.
- · Was missing the medication related to any substance use relapse?
- Without judgment, ask "Why did you miss the medication? Did you forget, or did you choose not to take it at that time?"

Reframe about non-adherence: Do not ask if they have missed any doses; rather ask, "How many doses have you missed?"

For clients who forgot, ask them to consider the following strategies:

- Keep medication where it cannot be missed: with the TV remote control, near the refrigerator, or taped to the handle of a toothbrush.
- Everyone has 2 or 3 things they do every day without fail. Put the medication in a place where it cannot be avoided when doing that activity but always away from children.
- Suggest they use an alarm clock set for the time of day they should take their medication. Reset the alarm as needed.
- Suggest they use a Mediset*: a small plastic box with places to keep medications for each day of the week, available at any pharmacy. The Mediset* acts as a reminder and helps track whether or not medications were taken.

For clients who admit to choosing NOT to take their medication:

- Acknowledge they have a right to choose NOT to use any medication.
- Stress that they owe it to themselves to make sure their decision is well thought out. It is an important decision about their personal health and they need to discuss it with their prescribing physician.
- Ask their reason for choosing not to take the medication.
- Don't accept "I just don't like pills." Tell them you are sure they wouldn't make such an important decision without having a reason.

- · Offer as examples reasons others might choose not to take medication. For instance, they:
 - o Don't believe they ever needed it; never were mentally ill
 - o Don't believe they need it anymore; cured
 - Don't like the side effects
 - Fear the medication will harm them
 - Struggle with objections or ridicule of friends and family members
 - Feel taking medication means they're not personally in control
- Transition to topics other than psychiatric medications. Ask what supports or techniques they use to assist with emotions and behaviors when they choose not to take the medication.

General Approach:

The approach when talking with clients about psychiatric medication is exactly the same as when talking about their substance use decisions.

- Explore the triggers or cues that led to the undesired behavior (either taking drugs of abuse or not taking prescribed psychiatric medications).
- Review why the undesired behavior seemed like a good idea at the time.
- · Review the actual outcome resulting from their choice.
- · Ask if their choice got them what they were seeking.
- Strategize with clients about what they could do differently in the future.

Special Packaging for Medications (Slides)

Special Packaging Color-coded yellow for morning, white for noon, orange for evening, and blue for bedtime.

Special Packaging

- Consumer's name, date/day of week/time, medication name
- · List of medications in each bubble
- Color coordination
- Easy open peel back instead of push through; no foil backs; no multiple vials
- Perforated and portable
- · Detailed with a medication listing at the top of each card:
 - · Directions from prescriber
 - · Description of drug shape/color/imprint
 - · Number of tablets/capsules in each bubble



Summary of Special Packaging

- Special packaging is an valuable tool for increasing adherence in the treatment of behavioral illness.
- Dispill® allows patients to understand their medications by allowing them:
 - To see their medications as one cohesive entity, not just multiple confusing vials.
 - · To make their regimen mobile
 - The capability of ease of package opening, i.e. instead of difficult to open vials
- Other options such as pill boxes, reminder packs, bubble packs, and strip packaging each focus on different parts of the adherence problem

genoa a Qo healthcare company

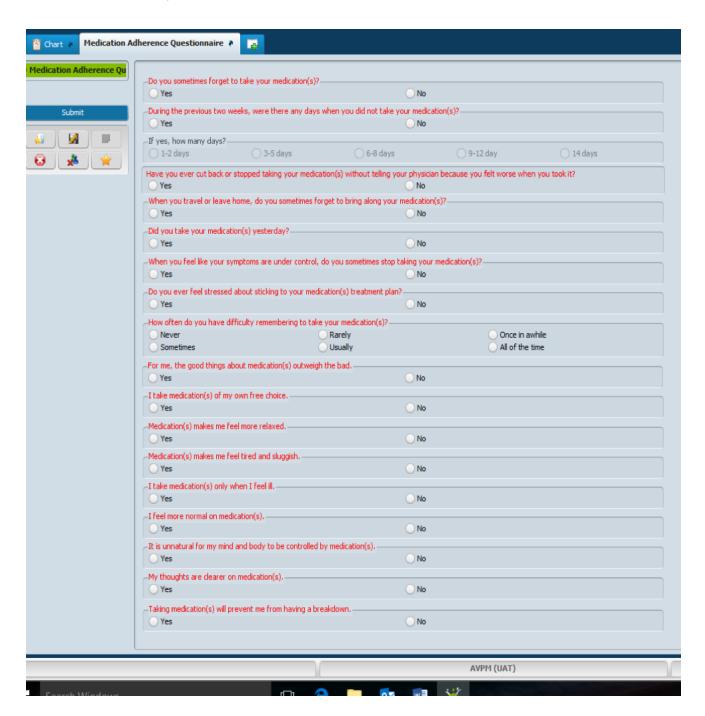
CFS Tulsa Adherence Barrier Questionnaire

During the last month	, nave you been prescrib	ed any mentai neaith medic	ations:			
OYes	ONo					
People may miss taking their medications for various reasons. Here is a list of possible reasons why you may have missed taking your medications.						
In the past month, how often have you missed taking your medications because:						
You wanted to avoid side effects?						
ONever	O Rarely	OSometimes	Often			
Of sharing medications with other family members or friends?						
ONever	O Rarely	OSometimes	OOften			
Of not fully understanding the medications and what they're for?						
ONever	O Rarely	OSometimes	OOften			
Of transportation problems getting to the clinic?						
ONever	ORarely	OSometimes	OOften			
Of lost or stolen pills?						
ONever	ORarely	OSometimes	OOften			
You had too many pills?						
ONever	ORarely	OSometimes	OOften			
You had a bad event happen that you felt was related to taking the pills?						
ONever	ORarely	OSometimes	OOften			
You forgot?						
ONever	O Rarely	OSometimes	OOften			

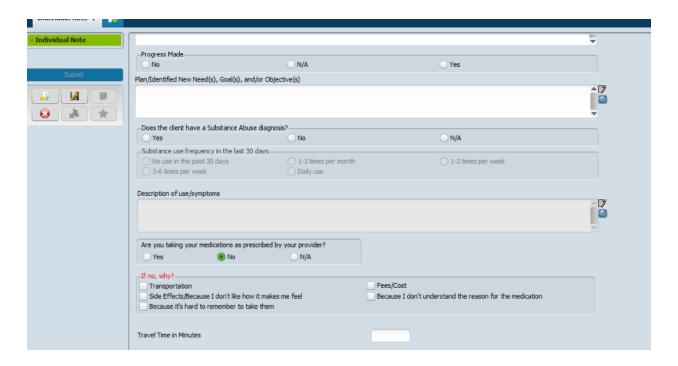
You ran out of pills?					
ONever	ORarely	OSometimes	OOften		
Of fear of being judged by others?					
ONever	O Rarely	OSometimes	OOften		
You were too ill (mentally or physically) to attend clinic visits to collect medications?					
ONever	ORarely	O Sometimes	Often		

Screen Shots From CFS Tulsa EMR

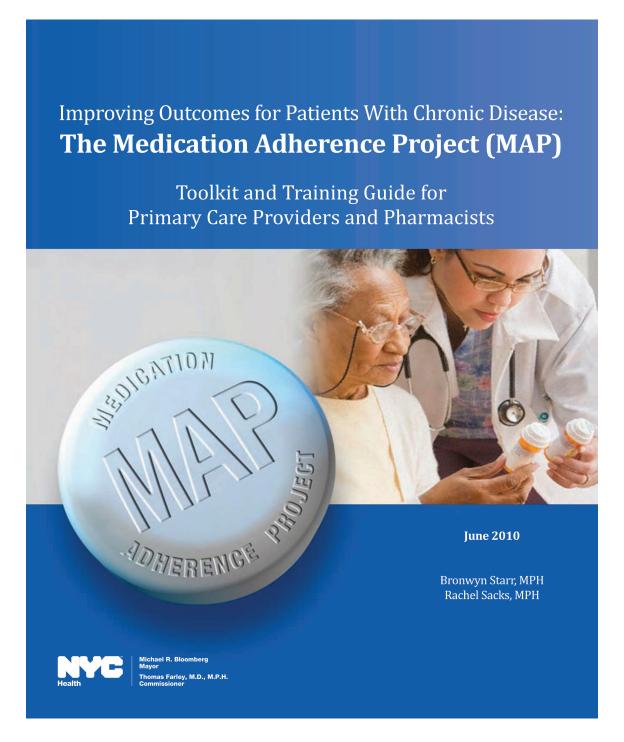
Medication Adherence Questionnaire



Individual Note, Adherence Question



The NYC Health Medication Adherence Project



Please refer to https://www1.nyc.gov/site/doh/providers/resources/public-health-action-kits-medication-adherence.page

Notes

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