



# Challenges with Adherence with Medical Care

# 29

Brenna Rosenberg Emery and Catherine Crone

## Introduction: Adherence in Organ Transplantation

One of the greatest challenges in discussing treatment adherence in organ transplantation is defining this seemingly simple term. Adherence has been called “a continuum, shaped through a complex interplay of influential factors at the individual and personal level” [1]. As defined by the World Health Organization (WHO), adherence is “the extent to which a person’s behavior, taking medications, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider” [2]. Definitions of non-adherence tend to focus on medication adherence despite the importance of other aspects of self-care, such as attending medical appointments, diet, and monitoring of vital signs. Thus, non-adherence can be loosely defined as any “deviation from the prescribed medication regimen sufficient to influence adversely the regimen’s intended effect” [3, 4]. Quantifying this “deviation,” however, can be challenging and varies greatly in the research community: missing, forgetting, or altering the dose of medication at least once per month; taking medications 2.5 h late at least once per month; and missing at least 10 or 20% of doses [3, 4].

Treatment adherence can be incredibly burdensome to patients. When asked about their own barriers to medication adherence, patients have reported a wide variety of concerns, including medication dosing and side effects, frequent clinic

visits or coordination with healthcare team members, regular changes to medication regimens, over-sleeping, effects on their ability to work, placing restrictions on their lifestyle, anxiety, and even perceived carelessness or forgetfulness [3, 5, 6]. Research suggests that patients with higher healthcare-related quality of life (HRQoL) are more likely to be adherent to immunosuppressant medications [7]. Likewise, patient perceptions of distress negatively affect HRQoL, adherence to medications, and subsequent graft survival [8–12].

There are high rates of non-adherence reported across all forms of transplants, from 22 to 68% [13]. Non-adherence has consistently been shown to predict morbidity and mortality in transplant patients [14]. Non-adherence with medications, specifically, is considered one of the most significant contributors to negative health outcomes and has been directly correlated with late acute graft rejection and graft loss [3, 15]. Measuring rates of non-adherence can be difficult, making validation of research around adherence particularly challenging and limited. Formal approaches to monitor adherence have varied. They include use of electronic pill bottles, radiofrequency identification (RFID)-tagged medications, review of refill records, measurement of serum drug levels, and completion of self-report surveys [3]. Self-assessment studies have reflected higher rates of non-adherence [5], although it is unclear if this is due to truly higher rates of non-adherence or if the patients’ perceptions of their own adherence differ from reality.

It is important, therefore, to view adherence as a behavior that is dynamic, rather than static, and that depends on the recommended regimens, geographical area, and cultural factors between the patient and the healthcare community [5, 14]. The WHO provides a framework for conceptualizing the factors affecting adherence for any chronic disease [2]. This has been adapted several times over the years since its publication in 2003 to specifically address the organ transplant community [1, 3, 4, 14, 16, 17]. These are summarized in Table 29.1.

**Healthcare system factors** represent the organizational structure in which the care is provided and how patients

B. R. Emery (✉)

Department of Psychiatry, Inova Fairfax Hospital, George Washington University, Falls Church, VA, USA  
e-mail: [Brenna.emery@inova.org](mailto:Brenna.emery@inova.org)  
[brennarosenberg@email.gwu.edu](mailto:brennarosenberg@email.gwu.edu)

C. Crone

Department of Psychiatry, Inova Fairfax Hospital, Falls Church, VA, USA

Department of Psychiatry and Behavioral Sciences, George Washington University, Washington, DC, USA  
e-mail: [Cathy.Crone@inova.org](mailto:Cathy.Crone@inova.org)

**Table 29.1** WHO risk factors for non-adherence in patients who have received a solid organ transplant [1–4, 14, 16, 17]

Risk factors for non-adherence	Subtypes (if applicable)	Specific factors
Healthcare system factors		Longer distance from the transplant center Rural location Access to care Public insurance status Communication between treatment team and patient
Clinical factors	Condition-related factors	Longer time since transplant Pre-morbid medical history Prior treatment non-adherence Type of transplant (organ type, donor type) Physical limitations Previous treatment failure, including prior transplants
	Therapy-related factors	Complexity and frequency of medications Side effects of medications Influence of the treatments on quality of life
Patient personal factors	Sociodemographic factors	Male gender Young age Non-Caucasian ethnicity Low socioeconomic status Education level Employment status
	Psychosocial factors	Feelings of distress, depression, anxiety Low self-efficacy Lack of supports (family, caregivers, social) Cognitive impairments and forgetfulness Negative treatment beliefs and satisfaction Substance use Poor health literacy Daily routine changes

access this care. **Clinical factors** are those related to the patient's health diagnoses and status (i.e., condition-related factors) and those related to the treatments for those conditions (i.e., therapy-related factors). **Condition-related** factors may include the patient's level of disability from the illness, the severity of symptoms, and the rate of progression of the illness. Some view this as pre-transplant factors to clearly differentiate it from **therapy-related factors** which are, by definition, post-transplant. **Therapy-related** factors refer to the aspects of treatment itself affecting adherence, such as medications. These can include the complexity of the medication regimen, side effects of the regimen, time to perceived benefit from the medications, and frequency with which these regimens may change. **Patient personal factors** are divided among those which are **sociodemographic**—such as sex, age, and income—and **psychosocial factors** which encompass the health beliefs, attitudes, and perceptions which influence the patient's motivation for treatment and resilience to stressors associated with care [1–4, 14, 16, 17].

These various factors can also be viewed as modifiable versus non-modifiable. Non-modifiable factors which have been associated with non-adherence include younger age, non-Caucasian race, increased time since transplant, and male gender. Modifiable factors which have been associated with non-adherence include poor social support, poor access to transportation or rural location, negative perceptions of

health or medications, public insurance (i.e., Medicare or Medicaid), poor health literacy, greater pill burden, and frequency of medication dosing [3]. This can be helpful when considering areas for interventions to improve adherence and when devising targeted interventions.

Screening and discussion with the patient about modifiable barriers to adherence should always be the first step in generating tailored recommendations for each patient. Lapses in adherence should be discussed openly and non-judgmentally with the patient. Rather than discouraging non-adherence, emphasis should be placed on the need for maximal adherence with treatment recommendations. Hu et al. emphasizes that published interventions focused on patient-level factors even though adherence is a multidimensional issue [18]. Further, validated interventions to improve adherence are rare. Therefore, a combination of interventions is recommended [1, 3] and no “one size fits all” approach should be used. The COMMIT (Consensus on Managing Modifiable Risk in Transplantation) Group suggests treating adherence as the “fifth vital sign,” which should be consistently evaluated at all clinical encounters [16]. Prior adherence is one of the best predictors of future adherence, especially regarding immunosuppressive medications. While there is significant variation across types of organizations and reviewing bodies on the specific details, it is consistently recommended that transplant clinicians evaluating adherence use a combination of methods to identify

these risk factors and, once identified, implement targeted interventions for modifiable ones.

There are four categories of interventions to improve adherence: (1) education around transplant-related information (e.g., medication instruction pamphlets, videos on life post-transplant, including medication taking), (2) behavioral interventions to promote medication adherence (e.g., pill reminders by text, cell phone apps, alarms, medication organization packaging or tools, establishing medication routines, simplifying medication regimens, or modifying them to minimize side effects), (3) psychosocial and emotional support (e.g., involving family members and friends, encouraging rapport building by treatment team members, involvement of mental health, substance use, or case management services), and (4) financial support (e.g., enrolling in medication assistance programs, enrollment in, and discussion of insurance coverage) [1, 3, 19].

Assessment of a patient's adherence should be considered prior to and following the transplant. Medication refill and health records (including routine medical appointments, emergency room visits, and dialysis sessions if appropriate) can be helpful for identifying adherence as well as lapses in regular care. Therapeutic drug-level monitoring and monitoring for development of new donor-specific antibodies (DSAs) should be considered. Various self-reporting scales exist to assess adherence. These can be used on initial screening and/or for longitudinal assessment. The Immunosuppressant Therapy Adherence Scale (ITAS) and the Basel Assessment of Adherence to Immunosuppressive Medications Scale (BAASIS) both assess medication adherence, while the Immunosuppressant Therapy Barrier Scale (ITBS) and Medication Adherence Barriers Questionnaire (IMAB-Q) assess barriers to medication adherence [16]. Clinician administered pre-transplant tools specific to assessing psychosocial factors which may affect adherence also include the Stanford Integrated Psychosocial Assessment Tool (SIPAT) [20], Transplant Evaluation Rating Scale (TERS) [7, 21], and the Psychosocial Assessment of Candidates for Transplant (PACT) [22].

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## Case History

Shawn is a 28-year-old, single, domiciled, unemployed African American woman with history of systemic lupus erythematosus (SLE) complicated by lupus nephritis and a psychiatric history of steroid-induced psychosis and adjustment disorder with depression. Shawn is in your office for psychiatric evaluation for a renal transplantation.

Shawn was diagnosed with SLE at age 24 after developing a butterfly-shaped rash on her face. She was reluctant to accept the diagnosis at first and was not adherent with medications until 6 months after her diagnosis. She was hospital-

ized at age 27 after going to the emergency room for lower extremity edema. She was found to be in renal failure, later confirmed by biopsy to be lupus nephritis. During this time, she was given high dose steroids. Shawn became psychotic and agitated during this hospitalization, though she did not require psychiatric hospitalization. She was discharged from the hospital with a short course of olanzapine 2.5 mg nightly and recommended to follow up with a psychiatrist in the community.

Shawn's renal function did not improve, and she was placed on dialysis about 6 months ago. Shawn was recommended for and is now interested in a kidney transplant. Shawn has not had any significant psychotic symptoms since hospital discharge but has started to experience moderate depression characterized by feelings of anhedonia, hypersomnia, weight gain, and at times hopelessness although she is future oriented overall. She has no prior history of suicide attempts or self-harm. She did not see a psychiatrist after her hospital discharge, nor did she continue taking any psychotropic medications. She is skeptical of taking new medications for her lupus and depression due to concerns about side effects, including becoming psychotic again. She admits that she recently started smoking cannabis nightly, due to feeling anxious and fearful that she will not get a transplant.

She now spends most of her days either taking care of her mother, with whom she resides, or attending to her own healthcare care needs. Most of her family and supports are out of state and, in Shawn's words, "living their own lives." She attends dialysis reliably three times a week. After careful review of her refill records, you see that she fills 30-day prescriptions for her immunosuppressant medications every 1.5–2 months. She has visited the emergency room twice since her initial presentation, once for anxiety and once for a refill of her immunosuppressant medications. She attributes her non-adherence to often being out managing either her own or her mother's medical care, causing her to forget to take medications.

She takes buses and the subway to her medical appointments. The collective household income for her and her mother is well below the federal poverty line, and both are Medicaid and Supplemental Nutrition Assistance (SNAP) recipients. Shawn lives in an apartment with her ill mother in a low-income area of a major metropolitan center in the northeastern United States. Shawn completed high school and worked in retail until her diagnosis with SLE. She drinks alcohol socially (1–2 times per month) and smokes cannabis, as discussed above. She otherwise denies any significant illicit drug or tobacco use.

## Clinical Questions

Within the WHO structure for risk factors for non-adherence, for each category (healthcare system, clinical, and patient personal risk factors):

1. What are at least two risk factors for non-adherence that should be considered in this case?
2. What are possible areas for monitoring or intervention to enhance adherence?

## Discussion

### Healthcare System

While income itself is an independent sociodemographic factor, it is undeniable that it helps “create the socioeconomic milieu of non-adherence” [3]. Access to services is often tied to the financial resources or supports one has. In a 2010 study of US kidney transplant programs, 70% reported that their patients have extremely or very serious problems affording medications, and 43% reported patients were not taking medications as prescribed because of the difficulty affording them [13]. Insurance status and ability to afford care also influences patients’ ability to even be listed for transplantation. Individuals with low incomes or non-commercial insurance (Medicare or Medicaid) report hindrances in completing a transplant evaluation and getting placed on the transplant waitlist. As of February 2020, Medicare covers approved immunosuppressive drugs under Medicare Part B. However, this coverage ends after 36 months for those younger than 65 who do not otherwise qualify for the program. This leaves many without financial means to afford expensive immunosuppressive medications after this window ends [23, 24]. Shawn is Medicaid recipient and lives below the federal poverty line, which may continue to be a barrier for her receiving pre-transplant evaluation and care. Linking Shawn as early as possible to case management and social work services will be critical for both improving and maintaining adherence.

In addition, transportation and distance to services have long been established as barriers to care for chronic health conditions, especially in populations with lower incomes or no insurance coverage [25]. In this case, Shawn lives in an urban region with good access to public transportation. While cost of transportation may be a barrier, she may qualify for transportation assistance through the city or state, should it exist in her region. Telemedicine, which has expanded during the COVID-19 outbreak years, may help patients overcome some of these system barriers.

### Clinical Factors

In the case of this patient, her prior adherence to treatment recommendations is a considerable concern. One meta-analysis in renal transplant patients found that 36% of graft losses were associated with prior non-adherence [26]. Prior

treatment adherence had historically been shown to strongly predict future treatment adherence [16], especially regarding adherence with prior recommended medication regimens and future immunosuppressant compliance [3, 27, 28] with some evidence that this does predict clinical outcomes, such as late acute rejection [3], likelihood of DSA formation [5] although recent findings have questioned that assumption [29].

Shawn has already had a significant new side effect from a medication (steroid-induced psychosis) and has expressed fears about medications causing serious side effects again. These are not entirely unfounded. Psychiatric adverse events are a common, if not anticipated, side effect of high dose systemic corticosteroids with mild to moderate reactions affecting about 1 in 4 patients and severe psychiatric disturbances in 1 in 20 [30]. Expanding to the general transplant population, patients often identify medication side effects as well as concerns about the long-term consequences of these medications as barriers to medication adherence. Immunosuppressant medications can cause a variety of drug-related symptoms [9] (e.g., hair growth or loss, trembling hands, tiredness, bruising, difficulty with concentration) and increase the risk for multiple medical comorbidities (e.g., hypertension, hyperlipidemia, diabetes, skin cancer, and lymphoproliferative disorders, osteoporosis, anemia, and gout) [31]. More complex medication regimens have also been shown to negatively impact adherence [5, 17, 27]. This has prompted clinicians to explore if moving tacrolimus dosing from twice daily to once daily may improve adherence and subsequent outcomes post-transplant [1, 3, 15, 16].

In addition, overall rates of non-adherence are highest in kidney transplant patients when compared to other solid organ transplants, 36 cases in 100 patients per year (PPY) versus 7–15 cases in 100 PPY in other types of solid organ transplants [14]. In a large meta-analysis, non-adherence rates specifically for kidney transplant recipients were 36% annually for taking immunosuppressant medication, 22–31% annually for lifestyle modifications (such as diet and exercise), and 5–15% annually for medical care requirements (such as appointment attendance and laboratory attendance) [14]. It is believed that these high rates of non-adherence in the kidney transplant population may be related to patient’s prior experience with dialysis and/or appreciation that organ failure may not be fatal. Research suggests that pre-transplant non-adherence, dialysis prior to transplantation, recurrence of underlying renal diseases, higher medical comorbidity, and lower self-rated health are all risk factors for non-adherence after kidney transplantation [4].

In this case, it is interesting that Shawn has been adherent with dialysis but not with recommendations for medications or psychiatry follow-up. It is important that this be explored with her to help her accept psychiatric interventions in the

future, should the need arise. Education with the patient as well as her medical providers about the risk of steroid-induced psychosis and the management of it may also be of value since it is likely she will require steroids in the future. Consultation with a pharmacist may also be helpful to provide education on the side effects of her medications—both current and future—and to develop behavioral interventions, such as alarms or pill boxes, to promote more regular adherence. Helping Shawn to understand the importance of medication adherence and tangible and relatable outcomes would be of value. Use of ITBS or IMAB-Q may be of value in the patient to make more targeted interventions.

## Patient Personal Factors

Shawn, unfortunately, carries significant risk factors for non-adherence due to patient personal factors. Formal assessment of these using one of the various psychosocial screens (e. g., SIPAT, TERS, etc.) may be of value in addition to clinical exam or chart review.

In general, specific sociodemographic are associated with medication non-adherence; these include younger age, male gender, non-white or Black race, low socioeconomic status, unemployment, education level, and poor perceived health and social support [3, 4, 14, 26, 32]. Shawn is young, has limited social supports, non-white, and with low socioeconomic status. Her female gender and education level (completed high school) are likely protective factors.

Assessment of health literacy formally could be considered, since this could be a factor contributing to why Shawn is adherent with some aspects of care but not others. There are a number of validated assessment tools in the literature: The Test of Functional health Literacy in Adults (TOFHLA) [33], the Newest Vital Sign (NVS) [34], and the Rapid Estimate of Adult Literacy in Medicine-Transplant (REALM-T) [35]. The Health Literacy Model in Transplantation (Heal-T) developed by Chisholm-Burns et al. presents an excellent structure for assessment of health literacy and making targeted interventions to improve it with transplant patients [36]. Health literacy is an important consideration, but an in-depth discussion of this concept is beyond the scope of this chapter.

Additional research is needed to clarify if there are direct, mediated, or more complex causal relationships between these sociodemographic factors and adherence. For example, evidence on the impact of minority race/ethnicity is mixed, with some studies demonstrating increased medication non-adherence in these patient groups [5] and others not [37–39]. One consideration is that the perceived effect may be more significantly influenced by other healthcare system and psychosocial factors, such as insurance status, income, and access to care, which all more directly correlate with non-

adherence [5]. Similar issues can be seen when considering the effect of a patient's education and employment status [3, 4] as well as psychological factors, such as stress and depression [37].

Prior substance use had been shown to strongly predict both post-transplant substance use and medication adherence [14, 40]. In one meta-analysis by Dew et al. [14] prior substance use treatment strongly ( $r = 0.62$ ) predicted post-transplant substance use. However, the rate of illicit drug, tobacco, and alcohol use remained very low (0.9–3.6%) when compared to other areas of non-adherence, such as taking immunosuppressant medication and exercising. Subgroup analysis of kidney transplant patients reflected similar findings. Literature on marijuana use, however, is limited. A single-center survey of kidney recipients found that 3% of patients used marijuana based on self-report or urine toxicology screens [41]. Another retrospective cohort study found 3% of kidney transplant candidates met criteria for cannabis abuse and dependence, with the severity of the cannabis use inversely associated with transplant listing [42]. Limited research does suggest that marijuana may affect tacrolimus levels through a drug–drug interaction with CYP3A4 enzymes [43], and inhaled cannabis has been implicated in increased risks of lung infection in solid organ recipients, including kidney [44].

Shawn's psychosocial risk factors are significant, though many are modifiable. She has a history of depression, anxiety, and psychosis, as well as poor adherence with prior recommendations for mental health care. Continuing to have Shawn be engaged with mental healthcare service will be critical. Support groups may be considered in addition to individual psychotherapy, both to help normalize her experiences and to find healthy coping strategies for dealing with depression and anxiety. Interval meeting with a psychiatrist should continue to assess if the use of psychotropic medications may be indicated. If she meets criteria for a substance (cannabis) use disorder, referral to addiction treatment programs should also be considered. The role of treatment of substance use disorders, including whether regular drug screening would be recommended, is discussed elsewhere.

### Take Home Points

1. While most often associated with medications, adherence can include all aspects of the recommended treatment plan, including dietary restrictions, regular exercise or activity, regular medical appointments and drug monitoring, and abstinence from illicit substances.

2. Non-adherence is a result of multiple dimensions impacting patients' health behaviors, including healthcare system, condition, treatment, sociodemographic, and psychosocial factors. These can be modifiable or non-modifiable.
3. Screening for and discussion of adherence should be a regular practice for patients undergoing transplant evaluation as well as following transplantation. Modifiable risk factors should be identified and used to develop targeted interventions.

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