Transplant Listing and Allocation – Alcohol Abstinence

Prepared by:

UNIVERSITY OF OTTAWA CENTRE FOR
Droit, politique et éthique de la santé
Health Law, Policy and Ethics

The Canadian **DONATION** and **TRANSPLANTATION** Research Program
Programme de recherche en **DON** et **TRANSPLANTATION** du Canada

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TRANSPLANT LISTING AND ALLOCATION – ALCOHOL ABSTINENCE

INTRODUCTION

Advances in immunosuppressive drugs and the refinement of surgical techniques have allowed for greater success and broadened the use of liver transplantation in humans since its initial attempt in 1963. Over the past decade, liver transplantation has increased for alcohol-related liver diseases. The need for donated livers continues to far outstrip available supply, meaning organ donation and transplantation (ODT) programs must allocate resources and prioritize candidates. Such a resource-limited environment forces the ODT system to make difficult choices between recipients in need. Generally, waitlists will prioritize the sickest patients, but other factors, such as the time spent on the waitlist, are also considered. Another important factor is utility – which means that ODT systems seek to derive the greatest possible benefit from the scarce transplant opportunities, and so likely prognosis post-transplant is also relevant.

ALCOHOL USE AND LIVER TRANSPLANTATION: CLINICAL IMPLICATIONS

Prior to receiving a transplant, potential candidates are put on an organ-specific waitlist such as the waitlist for liver transplant. Listing criteria can vary between liver transplantation programs. (1) Multiple factors can exclude candidates from liver waitlists, including alcohol use. Jurisdictions across Canada and the U.S. endorsed a 6-month abstinence rule for candidates in the 1990s, requiring individuals to abstain from any alcohol consumption for a 6-month period in order to be eligible for a liver transplant.

Two main rationales underpinned the initial use of the 6-month abstinence rule. First, it was believed that a period of abstinence might allow the damaged liver to recover, potentially negating the need for a liver transplant and its associated risks. (2) Second, a prolonged period of abstinence from alcohol pre-transplant was thought to decrease an individual's risk of returning to use post-transplant. (3) A return to drinking post-transplant could lead to worse clinical outcomes (like loss of the graft or death) as transplanted livers are more sensitive to alcohol effects leading to increased cirrhosis development. A 6-month rule was deemed clear and easy to apply in clinical settings.

CHALLENGING THE 6-MONTH ABSTINENCE RULE

The 6-month abstinence rule for liver transplants has been increasingly criticized in both medical and legal communities as candidates have been denied transplants or died during the abstinence period, culminating in several legal challenges. The heightened contention surrounding the rule is largely attributed to changing perspectives on alcohol use disorder (AUD). Previously, the disease was viewed as a self-inflicted personal issue, but is now primarily seen as a medical illness that requires appropriate treatments and supports.

WHAT IS ALCOHOL USE DISORDER?

AUD is a psychiatric illness defined as alcohol use causing clinically significant impairment or distress, characterized by impaired control over drinking and ongoing drinking despite harmful consequences.4 The Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5TM), classifies AUD as mild, moderate, or severe. The diagnostic categories from the previous DSM edition may be more familiar to physicians and the public: alcohol abuse and alcohol dependence.5 Alcohol use impacts several motivational mechanisms in the brain and progresses from positive reinforcement to negative reinforcement. (6) Ongoing alcohol use causes dysregulation in the brain reward and stress systems. (7) Alcohol misuse is common in Canadian society; approximately 14% of those aged 15 and older exceed the low-risk drinking guidelines for chronic risk and 10% exceed the guideline for acute risk. Additionally, about 2.6% of the population meets the criteria for more severe AUD. (8)

Alcohol use post-transplant can follow a variety of different pathways, including continued abstinence, the occasional lapse, a slow steady increase, or an early return to heavy drinking. Liver recipients who use alcohol post-transplant are more likely to demonstrate poor adherence to post-transplant treatment regimes, develop liver disorders such as steatosis or cirrhosis, or experience other health complications. (9)

Treatment for liver recipients experiencing AUD aims for remission, as complete recovery is rare. This approach works to manage risk by identifying any lapses early and initiating rapid treatment to prevent a return to problematic drinking. In order to prevent relapses, strong therapeutic alliances are needed between patients and clinical experts in substance use, mental health, and the psychosocial aspects of transplantation. Pharmacological treatments aim to reduce cravings and the pleasurable effects of alcohol consumption, while psychotherapies help patients target behaviours, develop coping skills, and build support networks. (10) The ease of access to culturally appropriate or, in fact, any treatment for AUD varies geographically in Canada.

A CHANGING LANDSCAPE: THE TRILLIUM GIFT OF LIFE PILOT PROJECT

As of 2021, several jurisdictions in Canada have completely or partially abandoned the 6-month abstinence rule and established alternative listing criteria due to criticisms of the former rule. The Ontario Trillium Gift of Life Network launched a pilot program in 2017 as an alternative to the 6-month rule for waitlisting liver transplants for patients with alcoholic liver disease. The Ontario program assessed patients with AUD who did not meet the 6-month rule using a multifactorial set of criteria (11) that aimed to evaluate a patient's risk of relapse on a more individualized basis. In addition, patients then entered treatment for the underlying AUD including both pharmacological and psychotherapeutic therapies. Long-term monitoring for adherence to post-transplant therapies and AUD outcomes were provided, with immediate referral to treatment in the event of a relapse. The Ontario program was considered a success and became permanent in 2020, and the results of the pilot program were published in 2021. (12)

LEGAL CHALLENGES TO THE 6-MONTH ABSTINENCE RULE

In recent years, the 6-month abstinence rule has been subject to legal challenge. The lawsuits highlight the tension between the principles of utility (allocate organs for maximal medical benefit) and equality (ensure fair opportunities for liver transplantation without discrimination) in ODT programs. The lawsuits point out that alcohol use disorder is highly stigmatized and argue that the 6-month rule perpetuates disadvantage related to disability as well as race. They argue that the 6-month rule was not evidence-based and was therefore arbitrary and in violation of the Canadian Charter of Rights and Freedoms. (13)

Three cases have, or are currently, challenging the 6-month abstinence rule in Canada.

WILLIAMS [14] AND SELKIRK[15] LAWSUITS

FACTS	Both Selkirk and Williams had alcohol-related liver disease and required liver transplants. Selkirk was denied waitlisting under Ontario's 6-month abstinence rule and passed away due to his illness in 2010. Williams was denied waitlisting under both the 6-month abstinence criterion and Ontario's alternate pilot program criteria, and he passed away due to his illness in 2019. Williams' mother and Selkirk's wife challenged the waitlist criteria under the Charter, and initially the cases were heard together due to their similarities. The Williams litigation was discontinued following changes to Ontario's criteria, but the litigation was continued by Selkirk.
ARGUMENTS	Selkirk argued that both the prior 6-month abstinence rule and the Pilot Program criteria were discriminatory. If a patient failed to meet the new criteria, they would need to demonstrate 6 months of abstinence to qualify.
OUTCOME	The Pilot Program was judged successful and permanently adopted in November 2020. In 2021, the Ontario Superior Court of Justice ruled that the pilot program criteria were constitutional. The Court did not make a ruling on the constitutionality of the prior 6-month abstinence rule.

UBCIC LAWSUIT [16]

FACTS	This case was brought forward by the Union of B.C. Indian Chiefs and continues a discrimination complaint initially brought forward by David Dennis to the B.C. Human Rights Tribunal before his death. The Tribunal dismissed the complaint due to Dennis' death, but the UBCIC is continuing the complaint as per his wishes.
ARGUMENTS	The Plaintiffs argue that the 6-month abstinence rule discriminates against Indigenous peoples by limiting their access to necessary healthcare, as Indigenous populations experience historically higher rates of alcohol use disorder. These higher rates are a product of the historical and ongoing legacies of colonialism and racism.
OUTCOME	As of June 2021, this case was ongoing.

LOOKING AHEAD

- **Address stigma**: efforts must be taken to continue to break down societal stigma surrounding AUD, especially conveying to the public how AUD is a chronic brain disorder. Public education and awareness campaigns are required in this area. (17)
- **Minimize regional inequalities:** national evidence-based guidelines and policies are needed to minimize regional inequalities and create cohesion across programs. (18)
- **Increase accessibility of substance use treatment:** leverage new technologies and offer remote psychotherapy consultations to improve availability for all Canadian communities in a culturally safe manner.

At the time of writing of this document, the Canadian Liver Transplant Network and Canadian Blood Services are working toward a national consensus practice guideline on the topic of alcohol abstinence and waitlisting for liver transplantation.

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