

abstainers who have very poor functioning (e.g. the sick quitter effect). Recent work among individuals with alcohol use disorder has found those with large reductions in alcohol use have functioning outcomes that are similar to, or even better than, outcomes reported by abstainers [16,17].

The definition of a 'negative consequence' also needs additional work in this field from a patient-reported perspective. There is some interesting work in the college drinking literature on whether individuals view 'negative' consequences as particularly negative [18]. Researchers might consider particular consequences as 'negative', but these consequences may not be perceived to be negative by the individual. This relates to the use of the term 'denial' in Kiluk *et al.* paper [1]. Is it denial when a patient does not view a particular consequence as negative? Or is the researcher asserting that the patient must be in denial because he or she does not view the consequence as negative? The development of measures to assess non-abstinence endpoints that are associated strongly with how a patient feels and functions ultimately need to consider the patient perspective and also take a broader perspective on what substance use behaviors, including reductions in use, might be associated with improvements in functioning.

Declaration of interests

None.

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Keywords Abstinence, alcohol use disorder, functioning, harm reduction, patient reported outcomes, substance use disorder.

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WHAT DEFINES A CLINICALLY MEANINGFUL OUTCOME IN THE TREATMENT OF SUBSTANCE USE DISORDERS: 'GETTING YOUR LIFE BACK'

Insights from the treatment of mood and anxiety disorders, the clinical neuroscience literature on addiction recovery and

evidence-based clinical practice in addiction treatments highlight nuances in substance-induced functional outcomes that ultimately depend on severity of substance use.

Kiluk *et al.* [1] pose a critical question to the field, which is whether we should be measuring a reduction in direct consequences of drug use or whether to focus on overall functioning to establish a clinically meaningful non-abstinence outcome. In contributing to this debate, we seek to highlight insights from the following research areas: (a) clinical outcomes for mood and anxiety disorders, (b) the clinical neuroscience of brain recovery from addiction and (c) evidence-based clinical practice in addiction. A starting-point is the assertion that substance use, consequences of substance use and overall functioning are deeply intertwined concepts, and that while focusing on non-abstinence outcomes, one must recognize that the nature and extent of any individual's substance use will ultimately impact consequences and overall functioning. Next, we will discuss insights from the three aforementioned lines of inquiry.

First, let us consider clinical outcomes for mood and anxiety disorders. The general practice in clinical research is to conduct diagnostic interviews prior to treatment and then to repeat these diagnostic interviews at the end of treatment. The assumption is that diagnostic interviews for mood and anxiety disorders are sensitive to change and will effectively capture symptom relief and associated functioning. This practice is much less common in the addiction literature, which leads us to consider (a) whether the diagnostic symptoms for substance use disorders (SUD) are in fact sensitive to recovery and (b) whether time-frames of assessment and the association between symptoms and functional outcomes can be adjusted to better fulfill these objectives. Elucidating the relationships between reduction in substance use and endorsement of specific symptoms may be an important question in determining functional recovery, and may vary by substance of abuse. In sum, addiction scientists should review the current diagnostic-based assessment criteria to consider whether these may be refined to meet the goals of capturing both substance use consequences and underlying functioning.

Secondly, we consider insights from clinical neuroscience of addiction. Neuroimaging studies have shown brain changes associated with the recovery process, as indicated by drug abstinence. Studies have demonstrated changes in dopamine metabolism as a function of prolonged methamphetamine [2] and tobacco abstinence [3]. Low dopamine transmission also predicts treatment failure among individuals dependent on cocaine [4] and methamphetamine [5]. While biomarkers are not yet sufficiently developed to serve as clinical outcome measures, they offer important insights into the recovery process. They highlight the notion that the passage of time and the level of drug use (in this case abstinence) are indicators of the recovery process at the

neural level of analysis. How much time and how little use is required to reach a given brain recovery outcome remains unknown. Whether the brain-based indicators of recovery reliably predict functional outcomes is an ongoing scientific question [6]. Nevertheless, the clinical neuroscience approach suggests that outcome assessments ought to include constructs of time and substance use quantity. This is consistent with the notion that individuals are most vulnerable to relapse within the first 3 months of recovery. These vulnerabilities may be mapped on to specific brain-recovery processes in future research [7].

Thirdly, a clinical outcome must capture insights from evidence-based clinical practice in addiction. A useful outcome must communicate to clinicians, patients and families that the individual is, in fact, better as a result of treatment and that changes in use, consequences and functioning must be observable. Clinicians have long recognized that individuals go through phases of recovery, including detoxification, early and prolonged recovery. These phases, in turn, parallel with clinical neuroscience insights regarding time of recovery as well as diagnostic considerations of early versus sustained recovery according to DSM5 criteria [8]. The general recognition that individuals have lower odds of relapse and improved functional outcomes with a longer passage of time in recovery should be included in the outcome process in order to capture confidence that the recovery process is likely to succeed. Over-reliance on a single data point, particularly during early recovery, can easily miss the mark on long-term benefits. This is critical as the field comes to recognize addiction as a chronic condition [9].

In summary, a valid outcome must be sensitive to clinically significant change at the level of the individual. Substance-induced consequences and substance-related functional improvements are subject-level constructs. We argue that the intersection between use, consequences and functioning across a span of time should be captured in order to fully ascertain the effects of treatments in individuals with a chronic condition, such as addiction. A vague but universal objective among individuals entering addiction treatment is to 'get their life back'. An outcome measure that can effectively capture improvements in one's overall quality of life will probably encompass dimensions of drug use/abstinence, functional outcomes, and the degree to which behavior changes have been sustained. How much of the individual's life they 'get back' should ultimately be captured by meaningful clinical outcomes.

Declaration of interests

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Keywords Addiction, evidence-based, neuroscience, outcome, recovery, treatment.

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HARM REDUCTION IN OPIOID TREATMENT: AN ESTABLISHED IDEA UNDER THREAT

Opioid substitution treatment and opioid treatment policy have often been driven by harm reduction rather than abstinence. Harm reduction is not without controversy, but has benefits in terms of patient health and public safety

Kiluk and colleagues argue that evaluation of treatment for substance use disorder has focused on abstinence rather

than reduction in consequences or functional improvement. They state that the use of such outcomes, rather than abstinence, is a recent development and is confined to alcohol treatment [1]. However, reduction in use, rather than abstinence, and harm reduction have long been end-points accepted in evaluation of maintenance opioid substitution treatment (OST). The majority of clinical trials supporting the use of methadone and buprenorphine maintenance used retention in treatment and reduction in opiate-positive urine tests as end-points, rather than abstinence [2]. In the United Kingdom, harm reduction guided opioid treatment policy for most of the 20th century [3]. Large government-commissioned longitudinal studies of patient outcomes such as the National Treatment Outcomes Research Study were used to justify continued support for methadone maintenance treatment because of reduction in drug use as well improvement in physical and psychological health associated with maintenance treatment [4]. A subsequent systematic review has shown that sustained opioid substitution treatment is associated with reduced mortality [5].

Drug harms also encompass harms to wider society, and in the United Kingdom it was these harms which drove large shifts in drug treatment policy [3]. Although maintenance prescribing was established and explicitly sanctioned in the United Kingdom from the earliest decades of the 20th century, by the 1970s it had fallen from favour and practice was variable across different drug clinics [6]. It was the discovery of high HIV prevalence among heterosexual injecting heroin users that reframed opioid dependence as a potential public health threat and drove expansion of OST prescribing services in England and Scotland [3]. Subsequent research has confirmed that maintenance opioid substitution treatment was associated with a decrease in HIV risk-related behaviours in people who inject drugs and is believed to have curtailed the spread of HIV in the United Kingdom. In countries where such a programme was not adopted, prevalence of HIV was higher [7].

The harm reduction approach in general has been challenged in the United Kingdom during the past decade by the Recovery movement, which has resulted in a shift in funding towards abstinence-orientated interventions [8,9]. Criticisms levelled at maintenance treatment were that it ignored service users' aspirations towards abstinence [10] and was antithetical to a goal of abstinence [11,12]. The rise of the Recovery-orientated treatment has been associated with some worrying developments: first, service users electing to reduce maintenance medication more quickly than prescribers recommended to speed their recovery with subsequent rapid relapse [13], and secondly, reduced take-up of take-home naloxone following prison release, as both health-care workers and service