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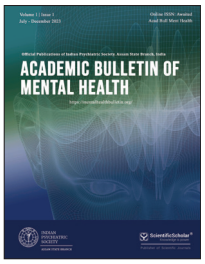

Review Article

Clinical Outcome Measures in Addiction Psychiatry

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ABSTRACT

Background and Aims: Several outcome measures have been utilized in addiction psychiatry. This paper discusses the various aspects of consideration for utilization and critical scrutiny of outcome measures used for various purposes in addiction psychiatry.

Methods: We followed a narrative review methodology to describe the various facets of outcome measures used, including the types of outcome measures, target respondents, validity, and applicability of the outcome measures.

Results: Varied forms of outcome measures have been used in addiction psychiatry, which can be schematically divided into substance use frequency and/or amount, the impact of substance use on functioning, quality of life, broad functioning measures, costs incurred on substance use, recovery capital, and recovery, composite directed measures self-report, diagnostic instruments, ecological momentary assessment, biochemical verification, and other ancillary outcomes. Each of the methods has its own strengths and contextual utility. One would also need to consider cultural aspects and purported utility while planning and implementing outcome measures.

Conclusion: Outcome measures have an important role in demonstrating effect and facilitating comparisons in addiction psychiatry, both in clinical trials and non-trial situations. Careful considerations for choosing outcome measures would enhance their utility.

Keywords: Trial, Naturalistic, Substance use disorders, Drug dependence, Clinical

INTRODUCTION

Outcome measures are important parameters of how the effectiveness of different intervention strategies can be measured.[1,2] For treatment to be deemed effective, they would have to be assessed on some measures, which preferably should be objective.[3,4] They also need to have a utilitarian value so that they can be actually used in the clinical or community setting. Intervention trials often have clear and well-defined outcome measures, which are measured at least at two different time points to show whether statistically significant and clinically relevant changes occur over time. Not only intervention studies but naturalistic studies may also be using outcome measures to demonstrate changes with time.[5,6]

For addiction psychiatry as well, several types of outcome measures have been developed and utilized.[7,8] Broadly, outcome measures are either self-rated or clinician-rated. Outcome measures have been developed targeting specific substances (for example, SADQ for alcohol) or broadly different substances and different domains (for example, Addiction Severity Index, ASI); for specific populations and in different geographical regions based on the local needs. Due to the multitude of outcome measures available, it may be challenging to select a valid and appropriate measure for evaluating outcomes.

Using outcome measures in the clinical setting requires some nuanced thought on the applicability, utility, and validity of the outcome measures. There is a wide range of outcome measures to choose from, and rational decision on the outcome measures has value for translating into good research and clinical practices. There is a lack of definitive guidance on the topic encompassing diverse considerations (including pragmatic and context-specific ones). Hence, the present narrative review lays out considerations for selecting and implementing outcome measures in the field of addiction psychiatry. Attention is also drawn toward the necessity and context of application of the outcome measures and the adaptations that are required in specific scenarios. The write-up intends to carry forth the discourse on the utility and utilization of suitable outcome measures in addiction psychiatry (and possibly psychiatry in general) and intends to build upon the information and arguments presented in other reviews.

METHODS

We followed a narrative review methodology on the use of clinical outcome measures in addiction psychiatry. The initial review of the literature was done by one of the authors (SS), which was supplemented by the other authors. The authors discussed and deliberated on the research studies to be included, based upon the central thematic broadly defined question of "clinical outcome measures in addiction psychiatry". Outcome measures were defined as any parameter that has been or could be potentially used to report or infer changes with interventions or naturalistically with time. The authors aimed to provide key insights and ideas, organizing the material into sections rather than providing exhaustive references on particular sub-topics.

The searches were done in the month of September 2023, using electronic search engines (primarily PubMed and Google Scholar). Searches were iterative using keywords related to "outcomes" and "substance use disorders"/"addiction". The qualitative synthesis of the material was done. Consideration for selecting and choosing the appropriate outcome measures was developed by the consensus of the authors.

RESULTS

What domains should be assessed?

One of the primary concerns is about what domains should be considered as an outcome measure. Substance use can be frequent or infrequent and may variably affect different aspects of life. The prime consideration here would be whether the substance use frequency or amount be the sole consideration as an outcome or should the outcomes be more comprehensive (for example, looking at the dimensions of impact on the family or employment).[4,9,10] Some of these approaches are exemplified in Table 1.

Table 1: Domains or aspects of outcome assessment in addiction psychiatry.

Domain of assessment	Examples
Substance use frequency and/or amount	Number of days of substance use in the last 30 days (Maudsley Addiction Profile)[11] Time Line Follow Back method.
Impact of substance use on functioning	Addiction Severity Index (ASI)[12] domains, namely, employment, family, social functioning etc.
Quality of life	WHO Quality of Life instrument[13]
Psychological functioning	Symptom Checklist 90[14]
Broad functioning measures	Global Assessment of Functioning[15]
Costs incurred on substance use	Assessment as a part of ASI, or self-designed questionnaires
Recovery capital and recovery	Substance Use Recovery Evaluator (SURE)[16] Assessment of Recovery Capital[17]
Composite directed measures self-report	Fagerström Test for Nicotine Dependence[18] Severity of Alcohol Dependence Questionnaire (SADQ)[19]
Diagnostic instruments	Mini International Neuropsychiatric Interview (MINI)[20]
Ecological Momentary Assessment	Visual analogue scales
Biochemical verification	Urine drug assays,[21] breath Carbon Monoxide levels
Other ancillary outcomes	Medication adherence, physical and mental health

Looking at only substance use may give an immediate idea about whether the person is currently using the substance or is abstinent. Getting information about whether substance use is happening provides some clarity about whether substance use continues to exist. In many substance-dependent individuals, intake of substances (or re-initiation) results in consequent problems in health and life. Substance use can be measured by frequency of use (like daily, few times a week, few times a month, etc.), number of days of use in the last month, number of days of heavy substance use (for example, heavy drinking days), or average consumptions. The project MATCH (Matching Alcoholism Treatments to Client Heterogeneity) used alcohol use and abstinence as an outcome measure.[22] The advantage of measurement in this manner is the simplicity of approach and discerning the relative frequency of each substance of use.

However, substance use per-se may not reflect that it is being used in a problematic manner. The problems caused by substance use in an individual's life can be assessed in several domains. A tenet of a psychiatric disorder is the

causation of dysfunction in social, occupational, or other aspects of life. Hence, the demonstration of the presence and trajectory of the substance use disorder would be to assess the impact due to substances (and each individual substance if possible) in specific domains of life – like social and family life, employment, physical and psychological health, issues with law enforcement, and others. ASI has been used as an outcome measure in opioid substitution treatment studies in both developed and developing countries.[13,23]

Another approach to ascertain the outcome is to look at ancillary measures. Quality of life measures can be used as an alternative to assess the overall quality of life and how it changes with time and/or intervention. This may be the more meaningful outcome and may enable cross-illness comparisons. Previous studies have looked at the quality of life changes in persons with substance use disorders.[13,24,25] Broad assessment of functioning may be assessed using the Global Assessment of Functioning, though this measure may be susceptible to significant subjectivity. Costs incurred on substance use may be of value for cost studies (they may be part of the intervention framework), and this may enable decisions to be made by the policy-makers. Researchers have assessed the cost related to substance use disorder interventions in their previous work on substance use disorders.[26,27]

One more way to look at the outcomes is in terms of recovery and assessment of recovery capital. Interventions, if they are effective, would lead to not only substance use cessation but is also likely to lead to recovery of the individual.[28] Substance use disorders are often considered as having relapsing and remitting courses, but recovery is often what individuals with substance use disorders aim for. Assessment of recovery capital can help individuals to know what resources they have (as per their appraisal) to cease substance use and bring substantive changes in their lives to lead substance-free or substance-limited lifestyles.[29] Recovery has been considered to be multi-faceted and challenging to define,[30,31] though studies have used recovery as a marker of outcomes of individuals with substance related problems.[32,33]

There are several scales developed for directed inquiry about specific substances. Scales like the Fagerström Test for Nicotine Dependence and the Severity of Alcohol Dependence Questionnaire (SADQ) can be used to assess the changes in the severity of specific substance use disorders with time. These scales often cater to specific substances and are able to discern the severity of changes with specific interventions. Previous interventional studies have used them as outcome measures.[34,35] The presence or absence of a diagnosis (including substance use disorder diagnosis) can be done using diagnostic instruments. They can be used to ascertain whether a diagnosis has reached remission within a period of time. Ecological momentary assessment (EMA) is another set of methods that enable "real-time" assessment of problems.[36] Often, one or two questions are asked several times a day or in different vulnerable situations to get an understanding of the present state of craving, consumption, or other parameters.

Another aspect of assessment may be the use of biological samples. The use of biological samples (urine, blood, saliva, hairs, breath, dried urine spots, etc.) offers objective and verifiable estimation of substance use.[3,37,38] This can help address any potential deviation from the actual pattern of substance use while gathering information from the patients. These biochemical parameters may have individual windows of detection and may require variable degrees of sophisticated equipment, based upon the precision of assessment required. Yet, they often are built-in as outcome parameters in trials individually or as a combination with other measures.[3] Previous literature has used reports from assessment from urine drug screens.[39]

There can be additionally yet another set of ancillary measures that can be used as outcome parameters.[40] These can include assessment of medication adherence, homelessness, fidelity to treatment or therapeutic approaches, patient satisfaction, engagement with treatment, and physical and mental health of the individual.

From whom should we ascertain the outcomes?

One of the important considerations is whether the outcomes should be reported by the person concerned (the individual who has been using the substances), should be rated by clinicians based upon the global information from family and acquaintances, or should be objective parameters and blood investigations. The use of additional sources of information, including laboratory tests, can help add to the quality and accuracy of information. Discrepancies have been noted between self-reports and laboratory-verified results.[41–43] The question may arise then which information to rely upon in such circumstances. There can be several approaches in such circumstances:

1. Rely more on the objective ascertained information/ancillary informants/biological samples: This may negate the effect of the amnestic recall of the use of substances and motivated answers (in order to please or avoid negative consequences). One of the limitations of ancillary informants is that they may have limited knowledge of the extent of substance use (especially if the substance use is sporadic). The limits of biological samples are that they may have a "window" of detection and require laboratory facilities and proper handling of the specimen.

2. Rely more on the self-reported outcomes: This has the advantage of ease of assessment.
3. Take multiple outcome measures and report outcomes individually: This may demonstrate discrepancies in the different outcome measures and churn out the divergence, if so applicable. This may also be able to demonstrate if improvements or changes occur differentially in different domains with time and/or intervention.

An approach to decide which measures to use is to make the best judgment call based on context and scenario. Such an approach considers the context where the outcome measure is to be applied. For example, in prison settings, objective biological measures of assessments may be more reliable than self-reported measures. In school settings, self-report measures may be fairly accurate.

Table 2: Uses of outcome measures in addictive disorders.

Clinical and research
Ascertain effectiveness or efficacy in trials
Understand naturalistic course and progression of addictive disorders
Documenting the "current state" of the patients symptoms or substance consumption
Facilitating cross-cultural and cross-regional assessments
Administrative and policy
Assessing "quality" of care
Tracking changes with administrative decisions
Auditing (especially insurance)
Mapping treatment outcomes in a geographical region or over time
Law enforcement

Local and cultural adaptations

Outcome measures have a utility value only if they are usable in the local context.[44,45] Many of the questionnaire-based outcome measures used have been translated and validated in different languages (for example, ASI and Alcohol Use Disorder Identification Test [AUDIT]). AUDIT has been validated in several languages, including Chinese, Korean, and French.[46–48] Validation of scales and instruments is a resource-intensive process, and there are several steps/aspects in the validation process.[49] When used in a different cultural setting, there are two main considerations that apply. The first one is about translation and finding semantic equivalences of the words. One may find challenges in finding the right words to convey the meaning in the other language where the scale is intended to be applied. Semantic (meaning) equivalence is desired more than literal translation. The second consideration is the applicability and need for modification based on cultural realities. Some instruments used to assess the severity of substance use disorder have focused on specific items (for example, ownership of an automobile) for scoring. The same might not be applicable in other cultural contexts. Thus, applications of instruments and questionnaires as outcome measures need to be cognizant of the cultural issues. Adaptations, modifications, and re-validations may be necessary for certain specific instruments.

Purported uses of outcome measures

Outcome measures can have several uses in clinical practice.[50,51] The use of outcome measures can be several in patients with addictive disorders [Table 2]. We can divide the purported use of outcome measures into two broad groups: clinical and research and administrative and policy-related. We would like to emphasize that these groups are not mutually exclusive and may be used concurrently in some situations. Still, the clinical and research applications include ascertainment of efficacy or effectiveness in intervention trials; discerning naturalistic course and progression of addictive disorders documentation in the usual clinical practice; and providing usable measures to facilitate cross-cultural and cross-regional assessments. From an administrative and policy perspective, the outcome measures can be used for assessing the quality of care and assessing changes in outcomes that occur with administrative and policy changes. Aligned with this is the utility of auditing (for insurance and other purposes), mapping service characteristics over geographies and over time. In addition, outcome measures can have value when used as a contingency in law enforcement approaches (for example, the individual diverted from the criminal justice system to treatment needing to show continued abstinence and improvement in psychosocial functioning). The kind of outcome measures that should be used for these parameters would need considerations of feasibility, utility, reliability, and validity as well.

When and how frequently to assess outcome measures?

Some of the outcome measures (including self-reported outcome measures and biological measures) have a time frame ascribed to their assessment. For example, the Maudsley Addiction Profile largely looks at the last 30 days; visual analogue scoring of the EMA is based upon here-and-now; while many urine cassette tests look at the last 72 hours of drug consumption. Many clinical trials have built-in urine drug screening every week to find out whether drug use occurred during the time period. Similarly, longitudinal studies may have monthly or even less frequent assessments of substance use and assessment of other assessment parameters. Thus, the frequency of assessment of outcome measures would be dependent upon the method used for the outcome

assessment the resources available for outcome assessment and the necessity and utility of the outcome assessment.

One important aspect while implementing outcome assessment is the cost. Cost is incurred in not only in monetary terms (cost of equipment, kits, papers, pens, digital devices, etc.) but also in terms of the time of the administrator, time of the respondent, making additional arrangements, housing of the records, and so on. Thus, one needs to have a clear reason for outcome assessments, balancing the needs, economy of expendable resources, and future benefits from the outcomes assessed.

Attention to validity and reliability

Reliability and validity of the outcomes is yet another aspect to be considered while choosing the outcome measures. While many treatises and reviews are available on the importance and varied aspects of reliability and validity measures,[52,53] we would like to draw attention to some of the working nuances of these parameters. One of the important aspects is assessing the face validity – whether the method ascertains what it intends to ascertain. In addition, content validity and convergent validity should be good enough with the measure being used. Attention is also drawn to inter-rater reliability, as instruments with poor inter-rater reliability are likely to give different results in the hands of different assessors. Similarly, a fair to good test–retest reliability suggests that the instrument performs well and much confidence can be expended on the inferences. Known reliability and validity parameters make data from the outcome parameters easier to compare to what is already known. Nonetheless, assessment measures for which reliability and validity parameters have not been hitherto established can also serve as useful outcome measures.

DISCUSSION

There are several outcome measures that are available to assess the outcomes in addiction psychiatry. The outcomes vary in the manner of ascertainment, the domain that they aim to assess, and the time and resource investment required.[7,54] The present review discussed some of the considerations for choice, utility, and pragmatic utilization of outcome measures. Outcome measures are necessary to demonstrate changes with time or interventions, though there can be other possible uses for these outcome measures.

Outcome measures should be prospectively considered, planned, and applied. Certain considerations while choosing the outcome measures are presented in Table 3 and Figure 1. The assessment of outcomes should serve a purpose and should be implementable in the given scenario. One has to consider the cultural and contextual aspects of the assessment of outcome measures (for example, assessing information about legal issues and past criminal activities under threat of detention at a hot spot is likely to elicit limited usable information and possibly incite the wrath of the respondents). Furthermore, the ethics of assessment of outcome measures need to be thought about. Coercing individuals to disclose sensitive information without ensuring adequate privacy and confidentiality of information could be on slippery ethical grounds. Using deceptive methods for outcome assessment is another gray area, which may become detrimental to the interests of the individuals with substance use disorders when the information obtained is used to decline services (for example, stopping take-home medications based upon positive urine drug tests).

Table 3: Recommendations for considerations while choosing outcome measures in addiction psychiatry.

Measures what is intended to be assessed
More than one measure may be complementary
Feasible in the setting
A fair degree of reliability
Cognizant of resource constraints, if any
Aligned to aims of use – research/clinical/administrative/policy, etc.
Culturally acceptable and applicable
Ethical – process of assessment and utilization of results
Results are accessible for use
Previous usage to facilitate comparisons

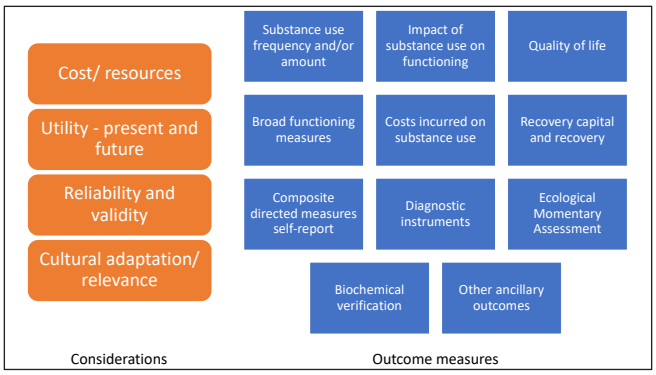

Figure 1: Considerations for the selection of outcome measures.

There abounds a variety of outcome measures, begetting the question of whether we need more. The answer to this question should probably be in the affirmative due to the reasons mentioned further. Firstly, cross-cultural issues exist in the application and inference of outcomes (especially self-reported measures). Hence, cultural adaptations of scales and measures, and the de-novo generation of instruments and measures have relevance. Secondly, improvements in measurement methods provide additional options in the armamentarium for assessment. While Point of Care tests offer an easy-to-use rapid measure, gas-chromatography, and mass spectrometry,

methods have enabled highly accurate detection of minute amounts of substances of use. Hopefully, in the future, we will be able to harness functional MRI to detect changes with time or interventions (and that may be used as a proxy outcome measure in research or practice). Similarly, other measures and methods may come up in the future. Thirdly, as the types of substances being used have evolved and the social-cultural milieu has transformed over time, the outcome measures and methods should also be aligned accordingly. To give an example, measures assessing barbiturates are rarely used nowadays, while synthetic cannabinoids have become the new focus of outcome assessment.

This narrative review has many limitations that the reader should be cognizant of. The narrative review methodology limits whether a different set of researchers would reach the same conclusions or inferences.[55] Also, the review is not exhaustive in terms of the types of outcome measures but provides examples and a scheme of classification. The review in places provides a viewpoint to the readers based upon the clinical experience. Nonetheless, we hope that the review will be of use to the readers to get an introductory understanding of the outcome measures in use in addiction psychiatry and base their choices on the outcome measures in accordance with the considerations enumerated.

CONCLUSION

Outcome measures are of much value in addiction psychiatry. They have an important role in demonstrating effect and facilitating comparisons. Several considerations (including technical, economic, and administrative) apply to the selection of outcome measurements. Selection of outcome measures are individualized and reasoned decisions, and the reasons should preferably be documented. There exists scope for the development of novel, contextually applicable, useful, and improvised outcome measures that are applied appropriately and provide useful information for decision-making.

Ethical approval

The Institutional Review Board approval is not required.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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