Review Article

# INTEGRATING SOCIAL & CLINICAL PARAMETERS IN OUTCOME MEASURES OF SCHIZOPHRENIA: A CLINICAL REVIEW

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## Abstract

Schizophrenia is a complex neurobehavioral disorder for which there are many promising new treatments. There is, however, a discrepancy in outcome measure reports when they are obtained from patients, relatives, caregivers, or professionals, thus making it difficult to determine the level of recovery. The reason for this lack of agreement may be due to the limitations of the measurement tools themselves, which are not comprehensive and may be measuring different aspects of outcome. Alternatively, it could be that the conceptual understanding of outcome and recovery require development. Unfortunately for one of the above reasons or both, patients assessed as “recovered” remain excluded from mainstream society. We are of the opinion that present outcome measures do not capture real-life situations. We propose that the concept of recovery be carefully defined and the gold standard of outcome should incorporate social and clinical parameters. We attempt to redefine recovery. Patients who have shown clinical improvement do not necessarily do well in everyday situations even though there is obvious clinical improvement. Therefore it has been repeatedly argued that a consensus should emerge and routine clinical practice should adapt to the criteria. We argue that the outcome measures should be multidimensional and consist of at least two parameters i.e. clinical remission and social outcome.

**Keywords** Outcome, Schizophrenia, Social, Clinical.

## Introduction

We have seen a revolutionary change in the manner in which schizophrenia is treated currently. It is the result of modern treatment that patients are able to live in the community. The understanding of 'improvement' has been a dynamic process. Historically it has two determinants i.e. the expectation of families in contemporary times and the treatments available. In the era of pre-neuroleptics the expectation was limited only to control of behavior, while today with range of treatments being available the expectations have changed. All the stakeholders involved in patient care tend to raise the bar and expect the patients to be as improved as one can be without having schizophrenia.[1] this review attempts to examine the argument for developing comprehensive and multidimensional outcome measures from the clinician's perspective. It advocates necessary consensus, need for objectivity and an integrated approach in expression of outcome. We have discussed current scenario of outcome status, followed by the role of integrated model of outcome on multiaxial parameters, which can convey 'real-life' situation of a patient's recovery.

Clinicians have the primary responsibility of deciding when to start the treatment and when to stop it. This can be a challenging clinical exercise to determine with certainty when a given patient has achieved what is possible to achieve. There is no consensus for evaluating 'recovery', particularly the 'recovery where medication still needs to be continued & the recovery where medication can be stopped'.[2-4] This clinical question has far reaching ethical, legal & clinical implications. Fundamentally, measurement of recovery needs to address these two questions viz. how should the recovery be defined and how the recovery should be assessed.

Description and expression of outcome in schizophrenia continues to cause confusion. Lack of consensus to define outcome, its essential parameters and their measurements continue to leave scope for subjectivity. It is also not clear if the outcome on different parameters represent different subgroups of patients. Patients who have shown clinical improvement do not necessarily do well in everyday situations.[5] Therefore it has been repeatedly argued that a consensus should emerge to outline criteria and the routine clinical practice should adapt to it.[6-10]

## Current scenario of outcome status

Outcome measures have been an intense area of research. Past research shows that schizophrenia is a heterogeneous disorder with a number of possible sub-diagnoses or sub-categories, each one associated with a different outcome.[11] Variable rates of outcome have been reported; both in short term & long term treatments from developing as well as developed world.[12-27] Several cultural, epidemiological and environmental factors play a

key role in determining the outcome. Despite lot of advancement in treatments and management, patients with schizophrenia consistently demonstrate more debilitating symptoms and outcome.[27]

The complexity in outcome research for schizophrenia patients arises from the fact that the disease is heterogeneous.[28] fortunately; outcome measures in schizophrenia have become progressively more objective. There is good outcome in short term treatment i.e. 12 weeks to 52 weeks studies, particularly those from randomized drug trials. Medium term studies also show a good outcome in the range of 40 to 60% and long-term studies show an outcome of less than 50%. However these figures are highly dependent on how the outcome has been defined.

A recent study of recovery in first episode psychosis from Netherlands shows that during preceding 9 months of a 2 years follow up 52% patients showed symptomatic remission, 26.4% functional recovery and only 19.2% met both symptomatic & functional criteria. Recovery was significantly associated with short duration of untreated psychosis and better baseline functioning.[5,29] One of our own studies of longitudinal follow up of first episode schizophrenia for ten years also showed that clinical recovery was achieved in 61% patients on clinical global impression scale. 25% were multiple clinical criteria and 26% social recovery criteria. Only 23% patients showed both clinical and social recovery.[30] In general it appears from several such studies that only 20% patients recover on both clinical and social parameters. About half of the patients who remit symptomatically or clinically do not gain functional recovery and minorities of 5-7% patients who gain functional recovery do not remit in symptoms.

It has been suggested that there is a significant difference of opinion as to which aspect of outcome is most relevant, depending on the patient, family members or clinician.[31] Outcome measures are evolving and recent additions in measurement now include measures in domains of psychopathology, quality of life & level of functioning.[32]

## 'Recovery' as Outcome

There was a time when standard discussion in the clinics used to be that schizophrenia is a life long illness with a down-hill course. It was also unfortunately acceptable that the patient may not get married, may not go to school or work. Someone in the family would be given the responsibility on moral arguments to of managing the person life-long. Parameters of independent living and quality of life were unheard of. The central theme of this paper is to concretize outcome parameters of clinical relevance. There has been several such proposals.[33-36] It is important to define which parameters would represent clinical recovery & which parameters would represent social recovery. We can then combine the two and formulate a set of functional outcome, which will certainly be more objective and standardized. We can then possibly achieve a 'language of outcome in schizophrenia'.

Scenario in schizophrenia management and expectation from treatment has changed remarkably, with contemporary social and cultural matrix. Outcome agenda has successfully traveled from symptom control to response, remission and finally recovery. Much of re-exploration of the concept of recovery is done in last ten years in psychiatric literature. Several definitions and several measurements of recovery have been proposed, and it is improvising and enriching on an ongoing basis. Threshold for acceptable limits of recovery is raising step by step.[37-42]

Antipsychotic drugs, which remain the mainstream treatment, work only in a small percentage of patients. Social and psychological therapies are conspicuous by their absence not only in developing world but also in most part of the developed world. Few centers of excellence and their research based outcomes provide encouragement, however typical response in community is never the same because of 'resource, funding and manpower constrains Even when a strong, qualitative and productive multidisciplinary team is available at work, only a small number of patients set the standards for employment and productivity. The literature suggests that recovery should be determined using functional and social domains among others.[43-44] These domains may be useful in determining recovery for a number of reasons: 1) because schizophrenia is a chronic and often debilitating incurable disease, symptoms and the associated distress fluctuates so that determining symptom severity at any point of time is clinically relevant. 2) One of the characteristic features of schizophrenia is social deterioration and functional decline. It is therefore necessary to measure outcome in terms of these domains. 3) Longitudinal research with antipsychotic drugs clearly shows that these medications can reduce symptoms and prevent clinical relapse, however, the effects of these drugs are not necessarily linked with social improvement. Social and functional outcomes therefore need to be assessed separately from gross clinical symptoms. 4) The economic cost of the disease needs to be evaluated. Accurate measurement of outcome can provide better cost/benefit estimations of any treatment. This in turn can help professionals determine the best course of treatment with the greatest benefit. 5) The advocacy movements that play some role in funding research and services in some countries insist on outcome information pertaining to adjustment to the community as opposed to institutions. Consequently, it is important to know how a patient is doing following discharge.

At present the international community already considers neurobiological, public health,

phenomenological, and treatment related issues with respect to determining outcome in schizophrenic patients. Historically understanding schizophrenia is been based upon dimensional and categorical dichotomies. Each one of these has their merits and limitations. The term recovery in schizophrenia has been defined in a dozen of different ways since a long time. Mental health advocates and policy makers are increasingly attuned to the importance of recovery concept, and psychiatrist and neuroscientists increasingly emphasize on medical model of schizophrenia. The key question remains, whether 'recovery' should be the outcome criteria? If so, how should it be defined? Studies have shown that people with schizophrenia are tremendously heterogeneous in each domain of recovery. Further various domains of recovery are by themselves relatively independent from one another. We reported that different patients recover differently of different parameters and correlation between these parameters remains poor. Because of this heterogeneity and independence of domains in recovery, Lieberman et all proposed defining recovery in specific domains rather than globally, for example 'recovery of cognitive functioning' or 'recovery of vocational functioning'.[45]

It has been repeatedly argued upon that outcome measures should be assessed on multiple parameters. However, no consensus has evolved regarding 'the minimum requisite number of parameters'. It is desirable to have broader parameters to capture as much information as possible in terms of domains. In this pursuit Meltzer in 1995 defined thirteen criteria for outcome, which appear very impressive and helpful.[46] Measures of outcome need to be more objective and replicable across regions and cultures. A survey of people with schizophrenia, their family members and health professionals reported seven categories of recovery. This study represents collecting understanding of recovery. The common denominator in various expression of schizophrenia was reported as 'recovery being a Process' and refers to recovery, which is gaining broader meaningful goals for individuals.[47]

There has been reasonable debate defining recovery. It is reported as a 'process', as well as 'recovery from illness', which gives an indication of cure. Recovery connotes complete absence of the disease. Current studies also emphasize 'outcome as return to normal function'. The other meaning is a broader dynamic process, where in, an individual has learned to cope with the illness, recognizes the limitations; makes attempt to define goals to pursue a meaningful life. Both these theorems are unrealistic and impractical. Both disregard scientific evidence of neurobiological changes and their irreversibility, and the psychological impact of the illness, which is also irreversible.

The emphasis on the range of improvement in specific area should allow clinicians to communicate more effectively on current scientific evidence and goals of treatment. A more pragmatic finding emerges from a Chinese study, which reports that full recovery could not be said to have been achieved until patients stop medication and have a steady job.[48] Traditional medical paradigm looks at recovery as resolution of symptoms or syndrome. The westernized definition is more of a narrative account of experience. These two views continue to remain conflicting.

Few facts about outcome of schizophrenia have been repeatedly replicated. Symptomatic remission, low hospitalization, less time spent during psychosis, low relapse rate are perhaps the most reported expression. The term 'favorable outcome' which has been widely used though appears technically vague has more rich descript. The 'science of recovery' has moved away from this descript to strategic quantification of domains. Though this paradigm shift is evidence based, it leaves a wide scope and vacuum while bringing objectivity in selection of parameters. E.g. if cognitive function is an independent outcome measure and it also mediates social and functional improvement, why it's being a measurement of end point is not enough for all three components?

The concept “central theme: recovery is only a sweet dream” reported by ..appears more realistic. It states that 'recovery is an ideal position where there is (a) no need for medication (b) higher psychosocial functioning; and (c) satisfying interpersonal relationship. The concept of full recovery is different for patients and for medical professionals. The latter can accept continuation of medication and still call it recovery if psychosocial functions are better

### Clinicians view point: Integrated model of outcome

The integrated approach provides expression, which is meaningful from clinical perspective. Clinician's work revolves around pragmatism as well as optimism. Clinician's agenda cannot be political, which demands social change in a broader sense. Goal of treatment continues to be what is doable and what is achievable. Therefore the parameters of recovery need to be redefined. We propose that at least two dimensions should represent the expression of outcome 1- Clinical outcome 2- Social outcome

It has been widely recognized that various settings may need to adopt criteria's and guidelines according to their requirements. Since a long time Psychiatric research has been using a set of criteria, which are defined and developed for use exclusively in research. Similarly a simplified set of criteria is also used in primary care for purpose of diagnosis and treatment. The objective of day-to-day service delivery cannot be allowed to be eclipsed by philosophical definitions of conceptual reorganization of a clinical state. There is an urgent

need for clarity as much as the need for doing away with ambiguity. Outcome measures of schizophrenia and understanding of recovery need not become akin to complexity of robotic science. While we recognize sophistication of thinking, need for inclusiveness and liberty for accommodating diversity, it is reiterated that psychiatry is a science and in that sense, discussion and discourse on recovery must remain focused, objective and practical. Clinical psychiatry is in need of criteria to measure outcome in schizophrenia to address real-life questions:

1. Has the patient improved sufficiently?
2. Is there a possibility of enhancing the state of recovery?
3. Is there a possibility of achieving more on a particular domain of schizophrenia?
4. Is there any treatment that may add value to patient's life?
5. What can be done to sustain what a patient has achieved?

We are of the opinion that parameters representing 'the illness' and 'the person' should be sufficient for outcome measurement. The current evidence of the neurobiological origin of schizophrenia and the psychosocial dysfunction vis-à-vis effectiveness of available treatments lays sound foundation for defining an achievable goal in management of schizophrenia. Based upon these goals the parameters of outcome need to be decided. Since a long time the criteria of 'return to pre morbid personality & functioning state' has been clinically utilized as an indicator of very good outcome. It was also observed that only few patients attained this state. We now understand that the aeti pathological process of origin of schizophrenia is far earlier that complete functional development of personality. Perhaps the patients of schizophrenia can never have a 'pre-morbid' personality because their personalities will always have a shade of illness. Recovery or outcome will continue to be measured 'in-relation-to' contexts. Absolute definitions are less likely to serve a clinical purpose.

The need for integration of parameters is evidence based and scientific. It is not possible to express outcome in a numeric expression on one single item. The bio psychosocial model to explain psychopathology itself explains its complexity and need for multiple parameters. Studies have shown that patients recover differently on clinical, social and functional parameters. Outcome is not a dichotomous expression. What one would like to know is not only if a patient has improved but also how much improved. Need for multiple parameters arises from multifactor origin of illness and its impact on multiple core areas of individual's life Therefore it is imperative that outcome should be measured and expressed on the parameters which have high sensitivity to represent viz. manifestation of illness i.e. fundamental symptoms and the limitation that the illness brings. Factors like independent living and ability to learn new skills would be the best representation of functioning.[49]

We also propose that out of several clinical criteria, APA taskforce recommendation is valuable and should form a necessary dimension. However, of all psychosocial, vocational and functional parameters that have been discussed, the decision of which parameter is representative of recovery in a given cultural context, should be left to the wisdom of local mental health professional. E.g. it is objectively difficult to measure 'employability' and 'employed' as outcome measures. In a culture, which is deprived and faces high unemployment, strict measurement of 'gainful employment' as outcome criteria would be questionable. Similarly in other conditions a person may have the employment without having achieved a state of 'employability' where the nature of work is scaled down because of secured social system.[50-57]

## Conclusions

Schizophrenia is a complex illness. Large number of patients has reasonable recovery. Discussion about meaning of recovery has gone far ahead with no consensus. Outcome criteria are representative of contemporary period; outcome goal now remain a state of recovery, which is a dynamic and evolving process. This continues to change with changing times. Different stakeholders have different expectations from outcome measures depending on their objectives. Clinician's perspective is to achieve a pragmatic and culture specific state of recovery, which we believe needs to be inclusive of clinical and social parameters. Nature of social parameters is highly culture specific and cannot be defined within a universal bracket. We expect a pharmacological breakthrough in treatment of schizophrenia, which may then change the recovery parameters.

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