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Amresh Shrivastava

University of Western Ontario, amresh.srivastava@sjhc.london.on.ca

Nilesh Shah

LTMG Hospital, Mumbai, India

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RESPONSE, REMISSION & RECOVERY: NEED TO REVIEW OUTCOME MEASURES FOR SCHIZOPHRENIA

Amresh Shrivastava¹, Nilesh Shah²

ABSTRACT

Schizophrenia is a complex neurobehavioral disorder known to be associated with poor outcome. It causes significant disability in patients and burden of care amongst relatives. Outcome in developing countries has been reported to be far better than western world, which has come into scientific scanner recently. Wide gap exists between expectations of outcome amongst patients, relatives, caregivers and professionals, which is possibly because of limitations in measurement tools. Significant number of patients remain marginalized without improvement in social & occupational functioning preventing their integration into mainstream of society despite 'clinically reported good outcome' and significant advancement in treatments. The contemporary outcome measure does not capture real-life situations. The concept of response, remission and recovery is being revisited scientifically. There is a strong need to develop culture specific, comprehensive and reliable outcome measures for schizophrenia, which reflects clinical and social outcome in multidimensional measures.

Key words: Schizophrenia, outcome measures

INTRODUCTION

Patients with schizophrenia consistently show poor course and outcome than patients with other psychotic and nonpsychotic psychiatric disorders (Jobe & Harrow, 2005). A significant difference in the concept of outcome among patients, family members & clinicians has been observed (McCabe et al, 2007; Kooyman et al, 2007). Recently, outcome measures have evolved and now outcome is measured in domains of psychopathology, quality of life & level of functioning (Burns, 2007).

It is repeatedly observed that outcome shown in research studies does not reflect real-life outcome status or a state observed in naturalistic clinical settings. It is also reported that poorly defined cohorts and weak study designs have hampered cross-cultural comparisons of course and outcome in schizophrenia. Best outcome from different countries vary between 34 and 62%. By and large at ten years the outcome is not more than 40-50%. In fact a ten year follow up study from the National Institute of Mental Health, USA concluded good outcome to be around 20%. Outcome in schizophrenia is a multidimensional measure; therefore it needs to be performed on different parameters (Faerden et al, 2008). The measurement of outcomes has risen in prominence over the past 30 years (Ellwood, 1988; Lohr, 1988). Standardized instruments have been developed which measure clinical aspects of illness, and more recently 'patient based measures' have been developed. In schizophrenia, standardized instruments traditionally define disease severity and change in clinical status by counting the number and severity of symptoms and signs - such as delusions and hallucinations ('symptom based measures' - e.g. Brief Psychiatric Rating Scale (Overall &

Gorham, 1962)). Patient based measures, however, assess the impact of illness on the individual (Jenkinson, 1994). These are often referred to as health status, health related quality of life (HRQoL) or functional status measures (Bowling, 1997). They measure more than just clinical symptoms, since they incorporate combination of the following domains: 1) physical health, 2) mental health, 3) social functioning, 4) role functioning, 5) general perceptions of health and well-being, 6) cognitive capacity and 7) patient satisfaction. Outcome measures have come to be used for a number of purposes, which include: 1) the evaluation of the clinical and cost-effectiveness of interventions in experimental situations such as trials, 2) the monitoring of population health, 3) clinical audit and 4) facilitating clinical decision making in routine practice and patient care (Faden & Leplege, 1992; Fitzpatrick et al, 1992; Fitzpatrick, 1994; Ware, 1995).

NEED FOR RE-EXPLORATION OF 'OUTCOME MEASUREMENTS'

The use of the term 'recovered' in outcome studies of schizophrenia has for a long time been problematic because of the many different definitions in use. While using the term (recovery) in the field of schizophrenia, a distinction should be made between symptomatic and functional recovery in order to place it in line with other fields of medicine particularly in long-term patients. It is suggested that the outcome needs to be measured on multiple dimensions, at least to reflect functional and symptomatic domains. There is wide consensus among researchers and clinicians that psychopathological domain alone does not reflect social situation. This attempt needs to be strengthened to capture real-life situations of patients in order to understand the factors, which prevent their social integration.

INDIAN CONTEXT

It was generally accepted that outcome of schizophrenia in developing countries is more favorable though reasons for the same were far from clear (Thara & Eaton, 1996). In Indian situation acute psychosis in short term has been found to have excellent course and outcome; however the belief that psychotic symptoms in schizophrenia are not just temporary states and have long-term impact was also supported. There is no clear evidence if such patients were able to gain social integration or not. Currently, this evidence also has been challenged and it appears that schizophrenia outcome is not as good as shown in several studies in the past, particularly in developing countries (Drake et al, 2006; Meltzer, 1995; Priebe, 2007). A possible selection against the most severe forms of schizophrenia could account for greater occurrence of better-outcome phenotypes (Kulhara, 1994). It is crucial to identify patients experiencing their first episode of psychosis who are likely to have an unfavorable long-term outcome. It is often seen that the outcome seen in clinical trials is reflected in clinical situation less frequently because of a variety of reasons. There is a wide variation observed in outcome status in different cultures and geographical regions as well.

LIMITATIONS

Clinical experience does show that patients suffering from schizophrenia continue to remain marginalized. They are seldom integrated in mainstream of society. A wide variety of outcome measures are used. The most frequent are clinical symptoms, hospitalization and mortality (direct indicators), and social/occupational functioning, marriage, social support and burden of care (indirect indicators). Areas such as cognitive function, duration of untreated psychosis, quality of life and effect of medication have not been studied in low and middle-income countries. Outcome in schizophrenia has many undesirable facets, longevity is reduced by 15 to 25 years, and mortality is high. About 40% of them die due to suicide and 60% die due to medical comorbidity; fewer than 10% remain in full-time productive employment. While documenting the heterogeneity in outcome and the generally poorer outcomes of patients with schizophrenia, studies also alert us to the danger of suicide and early death. In addition, they expose problems in clinical management and treatment and also help us anticipate the possibility of intervals or periods of recovery, some of which appear spontaneously and may be tied to individual patient factors such as resilience (Thara & Eaton, 1996). The routine measurement of outcome has not been without its critics (Crombie & Davies, 1997), and concerns have been raised that outcome measures are un-interpretable, unwieldy and a bureaucratic hindrance to successful patient care (Gilbody et al, 2002). One way in which the success or usefulness of outcome measures in everyday routine care might be judged is by evaluating

of the degree to which their adoption improves the outcome and quality of care. The results of research in other specialties has generally not been positive in this respect nor has the use of these measures been shown to improve the management of common psychiatric disorders in non-psychiatric settings (Gilbody et al, 2001). The measurement of outcome in the context of individual patient care is not without cost. Instruments must be developed, administered, coded, stored and retrieved - all of which have resource implication in terms of time, direct cost and opportunity cost. There is also a danger that outcome measurement triggers resource intensive interventions which are of no proven benefit to patients, and which might actually harm them. Perhaps, more subtly, there is also a danger that the uptake of outcome measurement in this context represents a marketing ploy, in which measurement is used to demonstrate an institution's 'customer orientation', but which does not inform the provision of care (Fitzpatrick, 1994).

EVOLVING CONCEPT OF OUTCOME

Concern has been raised in the way we measure the outcome status. It has been widely recommended that outcome should be at least measured on two dimensions, clinical and social. Much work on quality of life, global assessment of functioning and assessment of disability has been in this direction. Long-term and short-term studies do measure outcome of different dimensions; however, clinical practice and routine assessment still does not incorporate these measures. A recent expert panel has proposed consensus criteria for remission in schizophrenia. They distinguished remission from recovery, noting that the latter outcome was likely to require not only remission of symptoms, but also improvement in cognitive and psychosocial functioning. The panel deferred the task of establishing operational criteria for recovery since there was insufficient research on the topic (McEvoy, 2008). Treatment success in schizophrenia is multifactorial. These factors can be conveniently grouped into 3 categories: treatment-related factors, patient-related factors, and environment- or system-related factors (Buckley, 2008). Description of the long-term outcome of schizophrenia cannot be summarized with just one outcome variable. Recovery is now a widely discussed concept in the field of research, treatment, and public policy regarding schizophrenia. It has increasingly become a focus in mainstream psychiatry. However, it has also become clear that the concept is often used in multiple ways, and lacks a strong scientific basis. Recently some important questions have been raised in the literature: 'Do patients of schizophrenia ever recover?' and 'What do we mean by recovery?'. The use of the term 'recovered' in outcome studies of schizophrenia has for long been problematic because of many different definitions in use. While using the term in the field of schizophrenia, a distinction should be made between symptomatic and functional recovery in order to place it in line with other fields of

medicine (Ng et al, 2008). 'Recovery' is now a widely discussed concept in the field of research, treatment, and public policy in schizophrenia. As it has increasingly become a focus in mainstream psychiatry, it has also become clear that the concept is often used in multiple ways, and it lacks a strong scientific basis. A scientific basis is necessary for the concept of recovery to have a significant long-term impact on the way that schizophrenia is understood and treated. This scientific agenda for recovery includes (Cohen et al, 2008):

- 1) Differences in definitions of recovery and the implications of studying recovery processes and outcomes
- 2) Key research questions
- 3) The implications of data from outcome studies for understanding what is possible for people diagnosed with schizophrenia
- 4) Factors that facilitate recovery processes and outcomes, and methods for studying these issues
- 5) Recovery-oriented treatment, including issues raised by peer support. The role of hospitals in recovery-oriented treatment remains unexplored. Consideration of these issues may help organize approaches to the study of recovery, and in doing so, improve the impact of recovery-based initiatives.

'Response' in strict terms is defined as 'Often a response is the result of a stimulus', 'Remission' is defined as 'the state of absence of disease activity in patients with a chronic illness, with the possibility of return of disease activity'; while 'Recovery' may be seen within the model as a personal journey requiring hope, a secure base, supportive relationships, empowerment, social inclusion, coping skills, and finding meaning'. It is quite clear that recovery for schizophrenia is a state, which has not been given enough thought in terms of measurement. Parameters for recovery need to be scientifically defined based upon categories and dimensions that consist of the world of an individual suffering from schizophrenia.

MULTIDIMENSIONAL MEASUREMENT OF OUTCOME

A related development has been the introduction of formal 'needs assessment' tools in the care of those with severe and enduring mental illnesses, such as schizophrenia. Such needs assessment tools are intended to define health and social needs both at population level and, ideally, at an individual level (Thornicroft et al, 1992), so that healthcare provision might be more rational, responsive and 'appropriate' (Stevens & Gillam, 1998; Wright et al, 1998). Examples of individual patients' needs assessment tools for use in severe mental illness include the Camberwell Assessment of Need (CAN) (Phelan et al, 1995) and the MRC Needs for Care Assessment (Brewin & Wing, 1993).

Recently an expert panel has proposed consensus criteria for

remission in schizophrenia. They distinguished remission from recovery, noting that the latter outcome was likely to require not only remission of symptoms, but also improvement in cognitive and psychosocial functioning. The panel deferred the task of establishing operational criteria for recovery since there was insufficient research on the topic (Patel et al, 2006). Schizophrenia is different than mood disorder in course and outcome and any definition of remission in schizophrenia should reflect these characteristic differences. Schizophrenia has always been historically considered as an illness with no hope of recovery. It has been argued that refinement of knowledge regarding the clinical course of schizophrenia, improvements in psychotherapeutic techniques, and the introduction of antipsychotic medications began to alter this view, with consideration of possible parameters to define recovery appearing in the literature as early as 1983 (Ng et al, 2008). Psychosocial interventions including vocational therapies, family therapy, cognitive behavioral therapy, and rehabilitation have played a critical role in improving long-term outcome. Assertive case management has helped in preventing and resolving major social needs and crises in many western countries. Short-term outcome has been better in comparison to long-term outcome. Data also indicates that outcome deteriorates with time. In other words, there is a swing from recovery to non-recovery with passage of time, not necessarily relapse. Relapse is often accompanied by noncompliance with treatment or suboptimal treatment, which results in incomplete or uncontained symptom remission. Such condition may subsequently lead to chronic illness characterized by substantial morbidity and persistent deficits in cognition and psychosocial function. Some patients develop downhill course while others experience a relatively circumscribed deterioration (Issac et al, 2007).

It has also been reported that patient's perspective of outcome and recovery is far more different than clinician's and professional's perspective. In a study about stigma and discrimination in city of Mumbai more than 70% patients and more than 65% relatives expressed dissatisfaction about status of recovery in a group consisting of recovered patients with minimum 5 years of treatment and clinically classified as remitted by their respective physicians. It could not be ascertained whether these patients had the benefit of comprehensive pharmacological and psychosocial management involving a multidisciplinary team or not as they belonged to different clinical settings (Flyckt et al, 2006).

This discrepancy is a matter of concern for patients, care givers, relatives, researchers as well as service providers. It also needs to explore why such a gap in perception exists. It seems likely that if the individuals suffering from schizophrenia are integrated in main social stream at the end of the day, their expectations would be fulfilled and the gap would become narrow. In-depth analysis indicates that focus

of clinical setting often remains limited to response or remission in target symptoms and psychopathology while patients and caregivers wish to focus and aspire for family life, marriage, childbearing, employment, income generation and becoming free from liability of illness. It is in this direction that outcome measures need to be redefined in cultural context.

Recently there have been few attempts to look at this aspect scientifically, particularly from the working group of American Psychiatric Association (APA) on defining criteria for remission. Routine outcome measurement has been advocated as an adjunct to patient care within psychiatric services (Marks, 1998); where measures of psychiatric symptomatology might be applied in order to measure therapeutic response and to inform management decisions. In addition, broader measures of health related quality of life might also be usefully adopted. In the case of schizophrenia, impairments in quality of life and health status are often unrelated to the number or severity of symptoms (such as delusions and hallucinatory experiences) (Anthony & Rogers, 1995; Becker et al, 1993). This is especially important, since it is the level of symptomatology which forms the major focus of clinical consultations and practice, and is the major criterion by which the success or failure of treatment is judged in both practice and research (Revicki & Murray, 1994). Consequently, clinicians' perceptions of these wider problems are often poor and it has been empirically demonstrated that clinicians underestimate the health status or health related quality of life of patients when patients' and clinicians' ratings are compared (Becker et al, 1993; Lehman, 1983; Sainfort et al, 1996). The use of more comprehensive outcome measures, which capture both symptoms and wider health-related quality of life, might therefore be useful in identifying needs, monitoring clinical response and making clinical decisions in those with severe mental illness. The adoption of routine outcome measurement has also become central to government policy formulations. For example, in the UK, there have been a number of initiatives in recent years aimed at the introduction of outcome measurement tools into routine mental health practice, as part of a government health strategy to 'improve significantly the health and social function of mentally ill people'. In response, the Health of the Nation Outcome Scale (HoNOS) has been developed with a number of uses in mind, including the assessment of local service requirements and psychiatric morbidity at a population level (Wing, 1994). However, a key aim of the developers of the HoNOS is that it should be useful to clinicians in actual individual care planning, since without this feature it would not be widely used and the data which would ultimately inform decisions made at a population level would not be collected (Stein, 1999).

MELTZERS' CRITERIA

Meltzer defined 13 necessary outcome criteria for assessment of schizophrenia (Meltzer, 1995)

- 1) Psychopathology (positive symptoms, negative symptoms & disorganization,
- 2) compliance,
- 3) hospitalization,
- 4) suicidality,
- 5) extrapyramidal symptoms,
- 6) interpersonal social function,
- 7) cognition (six subtests),
- 8) work and employment,
- 9) social burden,
- 10) independent living,
- 11) aggression,
- 12) quality of life,
- 13) family burden

However no study replicated to measure outcome of all these criteria. Attempts are required to successfully integrate this measure into composite scale for easy understanding to define how different parameters can be converted to point out meaningful measures of outcome. In a recent study we reported a global recovery rate of 62% as per Clinical Global Improvement Scale (CGI) at the end of ten year period; however when we applied all 13 multidimensional outcome criteria by Meltzer's the recovery rate dropped to 55% in a group of clinically recovered patients and to 32% in the main cohort available at ten years for follow up. Further, even the recovered patients had significant disability. Large number of patients (between 30-45%) were living with one or the other positive or negative symptoms, varying degree of suicidality, neuroleptic side effects, limited social and personal functioning and family burden in Mumbai, contrary to earlier reports (Shrivastava & Thakkar, 2008). Several international studies of long-term outcome show a variable rate of remission between 33% to 50% from developed countries.

THE AMERICAN PSYCHIATRIC ASSOCIATION (APA) INITIATIVE

APA working group on remission criteria for schizophrenia has been a welcome move and much more is expected to be done. However in Indian conditions we require a culturally specific, sensitive, reliable, multidimensional outcome measure, which can be easily administered in wide variety of clinical setting by mental health professionals. Some of the important and relevant features of APA working groups highlighting conceptual framework, background and consensus criteria listed below are helpful in understanding the process of developing such a tool.

1. There now exists a range of pharmacological and non-pharmacological interventions with proven effectiveness, but with variable effect on specific disease features; pharmacological treatments are also characterized by substantial differences in the nature and severity of adverse effects. This variability highlights the need for and importance of establishing criteria for clinical improvement that can be applied across multiple treatment modalities and specific therapies (Andreasen & Olsen, 2005).
2. Although schizophrenia exhibits substantial heterogeneity with respect to severity and course over time, typical features of disease course have been summarized, with support from models presenting schizophrenia as a neurodevelopmental disorder with a substantial hereditary component. Attempts at early treatment have highlighted the significance of duration of untreated psychosis in first-episode schizophrenia (Kordy et al, 2002).
3. Although most patients improve significantly after their first episode is treated, the majority experience subsequent episodes, with only a small fraction being able to regain premorbid levels of functionality.
4. The APA practice guidelines reports a three-phase model of schizophrenia disease course, with the recognition that these phases merge into one another without clear boundaries. In this model, the 'acute phase', characterized by florid psychosis and severe positive and/or negative symptoms, is followed by a 'stabilization phase', during which symptoms recede and decrease in severity, and a subsequent 'stable phase' with reduced symptom severity and relative symptom stability.
5. According to these guidelines, 'the majority of patients alternate between acute psychotic episodes and stable phases with full or partial remission' although the operational criteria for remission remain undefined. Also unclear is the extent to which symptomatic remission must occur in order to achieve improved functioning and ultimately recovery and autonomy (Fallon, 1999).
6. Regardless of clinical course, it can be argued that current treatment perspectives are designed for, regrettably, preventing relapse, in contrast to therapy goals for which long-term symptom remission serves as a foundation for building functional gains.
7. The importance of defining a remitted state is highlighted by the observation that psychosocial therapies and rehabilitation are most effective when positive and negative symptoms are adequately controlled. The working group concluded that progress toward an operational definition of remission in schizophrenia is warranted at this time because of: a) The emergence of nuanced insights into the etiology, pathophysiology, and disease course in schizophrenia, b) the availability of effective psychotherapeutic and pharmacological options, c) the need to facilitate standardized comparisons across treatments and therapeutic modalities, and d) the opportunity that such a definition provides to elevate and more clearly articulate expectations on the part of patients, caregivers, and mental health providers for positive long-term outcome in schizophrenia.
8. Although the symptom-based criteria used in most of the studies represent a marked improvement over the generalized descriptions, the lack of consistent definitions prevents cross-study comparison and limits the generalization of results. Recent efforts to describe remission in schizophrenia have been based on longitudinal symptom evaluation combined in early-episode. However, most of these studies were not designed with the goal of establishment of operational remission criteria (Lieberman et al, 2001; Liberman et al, 2002).
9. The working group concluded that any definition of remission in schizophrenia should include a significant time component and be applicable to patients across stages of disease course. Categorical and dimensional approaches have important conceptual differences. Although categories divide patients into groups, dimensions divide symptoms into groups. Categorical approaches tend to have the problem that patients' disorders often do not present in classic "pure" forms. Dimensional approaches recognize the fact that symptom groups overlap in individual patients (Prevoo et al, 2003). It appears better to rest the definition of symptomatic remission on dimensional approach. The working group explicitly considered the incorporation of symptomatic, functional (activities of daily living, social relationships, employment, quality of life), and cognitive outcomes into the definition of remission. That is, functional improvement can occur in some patients in parallel with ongoing moderate symptoms, with some individuals developing coping mechanisms that enable them to function despite their illness.
10. Criteria: Three measurement scales were selected based on consensus: Schedule for Assessment of Positive Symptoms (SAPS), Schedule for Assessment of Negative Symptoms (SANS), Positive and Negative Syndrome Scale (PANSS) and Brief Psychiatric Rating Scale (BPRS). The SAPS, a 34-item scale used to assess positive symptoms in schizophrenia, is designed for use in conjunction with the 25-item SANS, which is used to assess negative symptoms (Yen et al, 2002). The Positive and Negative Syndrome Scale, is a 30-item inventory assessing the absence or severity of schizophrenia symptoms across three subscales (Andreasen & Olsen, 1982; Kay et al, 1987). The BPRS is an 18-item scale which is routinely used as screening tool (Overall & Gorham, 1962).
11. Based on an examination of these scales, the working group

identified appropriate criteria to serve as the basis for defining symptomatic remission in schizophrenia. In addition, the working group proposed that remission criteria might be described separately for positive and negative symptoms, to allow primary consideration of these symptom groups independently in the assessment of symptomatic remission. Specific items selected for consideration as criteria for remission in schizophrenia were chosen to map the three dimensions of psychopathology identified by factor analyses 1) Psychotism, 2) Disorganization & 3) Negative symptoms. With regard to severity, the working group consensus defined a score of mild or less (Positive and Negative Syndrome Scale item scores of ≤ 3 ; BPRS item scores of ≤ 3 , using the 1-7 range for each item; SAPS and SANS item scores of ≤ 2 simultaneously on all items) as representative of an impairment level consistent with symptomatic remission of illness.

12. Given the long-term course and intrinsic character of schizophrenia, the working group consensus defined a period of 6 months as a minimum time period of remission. Working group consensus provided that, in addition to meeting the criteria, individuals may remain in remission while experiencing minor changes in symptoms, in the absence of appreciable effects on daily function or subjective well being.
13. It was argued that data on cognitive dysfunction is less than adequate to incorporate it in outcome criteria.
14. Ongoing or emerging thoughts regarding self-harm or harm of others were considered to be a critical focus for clinical care. Implementation of these criteria should provide researchers and clinicians with a robust, well-defined outcome goal in the long-term treatment of schizophrenia, facilitating comparisons of effectiveness across therapeutic modalities.

Though these consensus criteria are very helpful, these have some limitations. The criteria address the features of symptomatic remission only, which is far from adequate. Social outcome has not been included possibly because research data on culture and region specific issues are not very robust. Similarly, cognitive dysfunction also does not find a place in outcome measures. It is being strongly argued to include cognitive dysfunction as a criterion for diagnosis in future diagnostic systems, DSM V and ICD-11. In this working group no consensus could be achieved regarding inclusion of cognition as outcome measure despite significant research data. Perhaps the data has not yet gained universal acceptance and rightly so. In a study we did not find significant cognitive impairment in a cohort of chronic schizophrenia with mean duration of 4.6 years (Shrivastava & Rao, 1995).

Summary Implications for practice

The use of outcomes measurement in the context of routine care of those with schizophrenia is unsupported by robust clinical evidence of the clinical and cost effectiveness of this strategy. Clinicians should judge for themselves whether the measurement of outcome and need is a reasonable use of their finite time and resources when the true value of this approach has yet to be demonstrated. For people with schizophrenia, invitations and edicts to complete and collect complex outcomes measures, questionnaires and needs assessment tools have not yet been shown to improve the quality of the care that those with schizophrenia and related disorders will receive. For policy makers, attempts to use the results of outcome measures in planning the care of populations with severe mental illnesses are likely to be frustrated or of limited value, when so few clinicians collect and use these data in the care of their individual patients. Policy edicts to collect and use these data may not represent the best use of clinicians' and patients' time and finite healthcare resources.

We propose that measurement of schizophrenia outcome needs to be necessarily done on three dimensions: 1. Persistent symptoms & side effects, 2. Social functioning & Social burden, 3. Independent living and productivity. This may possibly reflect correct outcome and will also be helpful in research and designing service delivery.

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1. **Dr. Amresh Shrivastava**, Assistant Professor of Psychiatry, (Corresponding Author), University of Western Ontario, Physician team leader- Early Psychosis Program, Regional Mental Health Care, 467, Sunset Drive, n5H 3V9, St.Thomas, ON, Associate Scientist, Lawson Health Research Institute, London, Ontario, Canada, E-mail: dr.amresh@gmail.com
 2. **Dr. Nilesh Shah**, Professor & Head, Department of Psychiatry, LTMG Hospital, Sion, Mumbai, India
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