

Developing an Outcomes-Oriented Approach for the Treatment of Schizophrenia

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The recent introduction of new antipsychotic medications has renewed hope and expectations that outcomes for persons with schizophrenia will improve and that more attention will be given to maximizing recovery rather than mere maintenance treatment. This article provides a framework for conceptualizing the complex range of outcomes relevant to long-term treatment of psychosis and provides some examples of the relationship of treatments to this outcomes framework. This framework can be used in developing better treatment programs. *(J Clin Psychiatry 1999;60[suppl 19]:30-35)*

We have moved into an era of renewed hope in the treatment of persons with schizophrenia. Arising from more than 3 decades of experience in serving these patients in the community rather than long-stay mental hospitals and spurred on very recently by the introduction of new antipsychotic agents, this renewed optimism is raising expectations for better outcomes and for progress toward recovery rather than maintenance care. Consumer and family advocates have become better educated and more outspoken about the need for treatment programs that promote better outcomes. The rhetoric of managed care has emphasized the concept of "outcomes management," referring to the efficient use of resources to produce the best outcomes. These pressures for better outcomes represent many potential advantages for patients and their families, hopefully providing the stimulus for greater societal investment in quality care. However, "outcomes" is a complex realm, often only poorly conceptualized and understood. In this article, I hope to provide a road map for thinking about outcomes of treatments and services for persons with schizophrenia and discuss some ways in which an outcomes framework can be used to improve care.

AN OUTCOMES FRAMEWORK

Previously, I presented a framework for thinking about the multiple dimensions of outcomes relevant to psychotic

disorders.¹ This framework incorporates the 4 major dimensions of outcomes identified by a National Institute of Mental Health (NIMH) expert panel: the clinical, rehabilitative, humanitarian, and public welfare domains.² The framework also emphasizes proximal and distal outcomes, terms that refer to both the causal immediacy of the outcome to the action of the treatment as well as the temporal proximity of the expected outcome to the application of the treatment. This implies a causal and temporal cascade of outcomes in which success with proximal outcomes may lead to success with more distal outcomes. Intervention effects for a treatment are likely to be stronger and more immediate on proximal rather than on distal outcomes. Nonetheless, distal outcomes may be of major importance to patients and their families, and hence even moderate effects on these outcomes may be important. Examples of 2 treatments, antipsychotic medications and vocational rehabilitation, will be used to illustrate this framework.

Most proximal outcomes of antipsychotic medications are in the clinical domain and include the reduction of positive psychotic symptoms (delusions and hallucinations) and the occurrence of medication-related side effects (Figure 1).³ The evidence that antipsychotic medications reduce positive symptoms is overwhelming. In aggregate, the randomized clinical trials of antipsychotic medications indicate that 75% of patients improved substantially while taking medication versus 25% taking placebo during acute episodes.³⁻⁵ Relapse rates on maintenance therapy are in the range of 15% to 20% in randomized trials versus 55% with placebo.³⁻⁵

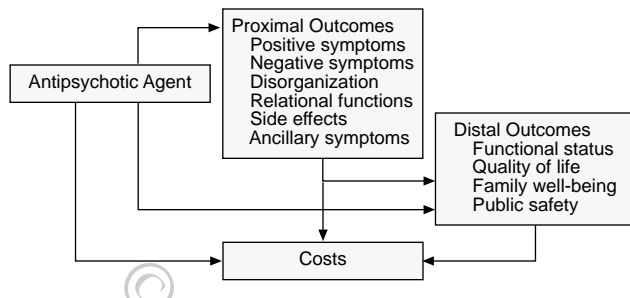
Proximal, clinical effects may also include effects on so-called "ancillary symptoms" commonly encountered among patients with schizophrenia, namely depression/dysphoria, anxiety, and irritability/hostility, as well as the other dimensions of schizophrenia psychopathology, such as disorganization, negative symptoms, and relationship

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Figure 1. Hypothesized Outcomes of Antipsychotic Agents



disturbances.³ The literature on conventional antipsychotic medications indicates that they exert, at best, modest influences on these other clinical dimensions, and their side effects may exacerbate some of these symptoms.^{4,5} There is hope that the new antipsychotic medications may have a more positive impact on these other symptom dimensions, but more research is needed.^{6,7} The new antipsychotics do appear to exert positive effects on ancillary symptoms, including depression and anxiety.^{8,9}

The hypothesized distal outcomes of antipsychotic medications (improved functional status, quality of life, and family and community welfare) require more speculation because these outcomes are often not evaluated and can be affected by other factors, including the natural course of the disorder, other treatments and services received, and a wide range of environmental influences. In theory, improvements in the primary psychopathology of schizophrenia may produce positive effects in the rehabilitative, humanitarian, and public welfare domains. For example, reductions in positive symptoms or improvements in cognitive disorganization related to an acute exacerbation typically allow patients to return to their level of functioning prior to the exacerbation. Unfortunately, this prior level of functioning is typically one of substantial disability due to enduring aspects of the disorder that are not responsive to antipsychotic medication, e.g., deficit symptoms. Whether newer antipsychotic medications are more effective in reducing long-term functional disability is an important question currently under intense evaluation. Other examples of hoped-for distal outcomes of antipsychotic therapy include enhanced quality of life, reduced family burden, and reduced costs.⁹

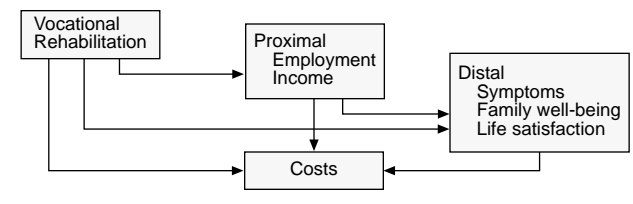
Data on the impact of antipsychotic medications on these distal domains—rehabilitative, humanitarian, and public welfare—are quite sparse and permit no conclusions. The data that are available pertain primarily to the relationship of symptoms to functional status and life satisfaction (Table 1). Life satisfaction has a negative relationship to depression, negative symptoms, positive psychotic symptoms, and akathisia.^{8-10,12} Functional status (e.g., Global Assessment of Function scale results) and positive attitudes about drug therapy have positive relationships to life

Table 1. Correlations of Clinical Domains and Life Satisfaction

Clinical Domain	Correlation
Positive psychotic symptoms	-0.35 ⁸
Negative symptoms	-0.57 ⁸
Depression	-0.42 ¹⁰
Deficit symptoms	+0.25 ⁸
Akathisia score	-0.39 ¹¹
Global Assessment of Functioning score	+0.28 ¹¹
Drug attitude score	+0.45 ¹¹

^aA.F.L., unpublished data, June 1997.

Figure 2. Hypothesized Outcomes of Vocational Rehabilitation



satisfaction. Psychotic symptoms have a less strong, but still negative, relationship to life satisfaction than do mood symptoms.^{10,12} An intriguing finding is that primary deficit symptoms show a modest positive relationship to life satisfaction, suggesting that the indifference associated with the deficit syndrome may spare some patients the anguish of insight. With regard to functional status, negative symptoms and cognitive impairment appear to relate more strongly to impaired functional status than do positive symptoms.^{10,13-15} Taken together, these limited data suggest that any improvements in quality of life and functional status imparted by an antipsychotic agent may be mediated through reduction in ancillary depressive symptoms and negative symptoms, and to a lesser extent, through reduced positive symptoms. Thus, antipsychotic agents that are more effective at reducing dysphoria and negative symptoms may produce better distal outcomes.

Turning now to the outcomes of vocational rehabilitation, Figure 2 displays some hypothesized proximal and distal outcomes of this type of service. The proximal outcomes of vocational rehabilitation include employment and income. Improvements in employment and income may enhance distal outcomes such as quality of life, family well-being, and clinical status.

Bond reviewed 23 experimental studies of vocational rehabilitation programs.¹⁵ He concluded that vocational rehabilitation interventions enhance several proximal vocational outcomes, but no study found advantages in competitive employment. A number of studies found advantages for vocational interventions on a variety of vocational outcomes including paid employment, full-time employment, job starts, duration of employment, and earnings, but none showed statistically significant advantages in competitive employment. Bond's major conclu-

sion is that "These programs have succeeded in placing clients in jobs and in helping clients retain these jobs. The consistent deficiency of these programs has been their failure to prepare clients for future competitive employment outside the support provided by the rehabilitation program. Thus, the success of vocational programs has been in helping clients adjust to a specific vocational environment, which has sometimes been sheltered or transitional employment."¹⁵(p250)

Two studies not reviewed by Bond provide additional information about the effectiveness of vocational rehabilitation interventions. A quasi-experimental study in New Hampshire¹⁶ compared vocational outcomes for 2 programs, 1 a supported employment program and the other a traditional partial hospitalization program. Patients in one town, which converted its partial hospitalization program to a supportive employment program with close coordination with a clinical service team, had significantly better vocational outcomes compared with the patients in the other town, which offered partial hospitalization. During the follow-up year, the supported employment patients increased their competitive employment rate from 25% to 39%, compared with no change among the partial hospitalization group. The supported employment patients also worked more hours and earned more wages compared with the partial hospitalization group.

A more recent replication of this intensive supported employment approach conducted by Drake and colleagues (R. E. Drake, G. J. McHugo, R. R. Bebout, et al., unpublished data) yielded similarly promising results. One hundred fifty-two chronically mentally ill subjects were randomly assigned to either the intensive supported employment approach or to standard "vender" private vocational rehabilitation agencies and were followed for 18 months. Supported employment participants were more likely to become competitively employed while the standard vocational rehabilitation participants spent more time in sheltered work. Interestingly, the 2 groups were equivalent on total wages and job satisfaction. These additional studies support the previous conclusion by Bond that vocational rehabilitation enhances employment rates among persons with psychiatric disabilities. The Drake study suggests that supportive employment closely coordinated with clinical care can enhance the rate of competitive employment among these patients, an encouraging finding in light of the less favorable results regarding competitive employment outcomes in prior vocational rehabilitation studies.

Considering nonemployment distal outcomes of vocational rehabilitation, Bond¹⁵ concluded that vocational interventions are associated with reduced hospital admissions. Nine of 17 studies that used rehospitalization as an outcome found an advantage for the patients receiving a vocational rehabilitation intervention. He points out that the nature of this relationship is difficult to ascertain be-

cause vocational interventions often are linked in these studies to various, poorly described clinical interventions. The Bond review also cites evidence about the impact of vocational rehabilitation interventions on outcomes other than hospital recidivism. Kuldau and Dirks¹⁷ reported that, compared with patients in the control group, those receiving vocational rehabilitation were more likely to be taking antipsychotic medications at 18-month follow-up. Although not presented according to diagnosis, the vocational rehabilitation patients at 18-month follow-up were more likely to have activities with friends and a valid driver's license. The vocational rehabilitation patients were also less likely to be "heavy drinkers." Hence, there is evidence that vocational rehabilitation may have a positive impact on distal outcomes, including clinical status and social participation.

CONCERNS ABOUT DISTAL OUTCOMES

Clinicians are quite used to thinking about proximal clinical outcomes of treatments, but may find distal outcomes in the rehabilitative and humanitarian domains more difficult to relate to their practice. To shed more light on these distal outcomes, consider the concept "quality of life." Although definitions vary, the quality-of-life concept encompasses a person's capabilities (functional status), access to resources and opportunities to use these abilities to pursue interests, and sense of well-being. The former 2 dimensions are often referred to as objective quality of life and the latter as subjective quality of life. Within these overarching dimensions of quality of life, life domains have been identified, such as health, family, social relations, work, financial status, and living situation.¹⁸ Quality of life is thus a complex notion. Improvements in quality of life are often cited by patients and families as their ultimate outcome of concern.

Two common concerns raised about assessments of quality of life include the validity of patient self-reports on their quality of life¹⁹ and the sensitivity of quality-of-life measures to change.²⁰ It has been repeatedly demonstrated that the so-called objective and subjective aspects of quality of life are not highly correlated. For example, income typically does not predict life satisfaction.²¹ The maxim, "You can't buy happiness," seems to hold. Nonetheless, most researchers also seem to view the subjective aspects of quality of life as central to the concept.²² Otherwise, one is left with measures of functional status and standard of living, that is, of the objective aspects of quality of life. There is little problem with this bipartite notion of quality of life when objective and subjective quality of life more or less correspond. For example, studies showing that patients report greater life satisfaction when out of the hospital than when in the hospital provide a consistent picture and little conceptual dissonance. The picture, however, is more confusing when objective quality-of-life conditions

and life satisfaction do not point in the same direction. There are numerous examples of this. In my own research, I have found that patients with schizophrenia, though functionally more impaired, express somewhat greater life satisfaction than do depressed patients.¹⁰ Others have found the same.^{11,19} Similarly, we have found that African American patients report lower incomes and rates of employment but somewhat greater life satisfaction than do white patients.²³

Another gnawing issue in the assessment of quality of life for persons with mental disorders is whether these persons can provide truly valid assessments of their quality of life. On a general level, it can be argued that psychometric studies of the validity of quality-of-life measures for persons with mental illness have produced positive results.²⁴ That is, these studies have tended to support the construct, predictive, and criterion validity of quality-of-life measures. Still, concerns frequently arise when quality-of-life findings do not coincide with investigator or societal expectations or logic. We must assume that there is something to this concern. As mentioned earlier, we do know that disorders of mood substantially affect the level of life satisfaction. Mood may also affect self-assessments of functional status. For example, a depressed patient may report low life satisfaction and cognitively distort and underestimate prior work achievements. Conversely, psychosis on average is only modestly related to levels of life satisfaction,^{10,11,19} probably because the effects of psychosis on life satisfaction depend upon the nature of the psychosis. Grandiose delusions may raise life satisfaction, while persecutory delusions will lower it. By definition, psychotic persons may distort the reality of their level of functioning.

Studies are needed to examine in more detail the relationships between quality-of-life judgments and psychopathology. A variety of research questions can be raised. How do persons' ratings of their quality of life vary when they are and are not experiencing major symptoms? That is, holding objective life circumstances constant, how does life satisfaction vary with symptoms? If it does vary, how should this variation affect the timing for collection of life satisfaction assessments? Holding symptoms constant, how does life satisfaction vary across time as changes occur in objective life circumstances? Does psychopathology override the impact of actual life circumstance changes on life satisfaction? Does depression dampen the effects of improvements in objective life circumstances? Does psychosis distort changes in life satisfaction related to changes in life circumstances? For example, do we see expected changes in housing satisfaction among the homeless who are psychotic when they achieve decent housing? Many of these questions could be answered from reanalyses of existing data sets or from longitudinal studies that concurrently assess psychopathology, life satisfaction, and objective life changes.

Further complicating this discussion, a recent study suggests that there may be a strong hereditary component to "happiness."²⁵ These investigators found intraclass correlations on a measure of subjective well-being in the range of 0.44 to 0.52 among monozygotic twins, whether reared together or apart, contrasting with correlations of -0.02 to 0.08 among dizygotic twins. Therefore, we must ask, "Is quality of life a state or a trait?" In contrast to the prior question about the impact of current mental status (a state) on subjective well-being, it is also valid to ask whether life satisfaction is primarily a function of enduring personality characteristics. In essence, are people inherently optimistic or pessimistic, and is this trait the main determinant of life satisfaction? Again, this question should be examined through longitudinal studies to determine whether and how life satisfaction changes as circumstances change. Do people have an internal set point for life satisfaction to which they tend to return despite changes in objective life circumstances? How should this be incorporated into ongoing quality-of-life evaluations? Some data suggest that such enduring temperament characteristics may affect measures of general life satisfaction more than measures of domain-specific life satisfaction, such as housing or job satisfaction (R. E. Drake, G. J. McHugo, R. R. Bebout, et al., unpublished data, and references 26–28).

TREATMENT WITH A DISTAL OUTCOMES PERSPECTIVE

Chronic disorders require a different approach to outcomes than do acute disorders.¹⁸ For acute disorders, the primary outcomes are proximal, the elimination of the signs and symptoms of illness and return to prior level of function and quality of life. Distal outcomes are generally not targeted. For example, treatment of an acute stress reaction seeks to eliminate the symptoms of distress and rapid return of the patient to his or her status prior to the stress. The situation with chronic, disabling disorders differs from this. Although proximal clinical outcomes remain critical (reduction of symptoms, minimization of treatment side effects), the distal outcomes that pertain to disability (functional status and quality of life) become more salient concerns of treatment. These distal outcomes are extremely important, but complicate the identification of treatment goals and the assessment of treatment effectiveness. Therefore, consideration must be given to how to approach these outcome goals. The essential steps to this process include identification of needs and agreement between the treatment provider and the patient about which of these needs can and will be addressed by the treatment, ongoing monitoring of outcomes, and ongoing readjustment of the treatment plan based upon outcomes (Table 2). Each of these steps requires some discussion.

Table 2. Applications of Outcome Assessments in Clinical Practice

Identify patient needs
Establish treatment and service goals
Monitor quality improvement programs
Supply provider "report cards"

Identification of Needs and Treatment Goals

Needs can be viewed as the starting-point correlates of outcomes, and needs may exist in the clinical, rehabilitative, humanitarian, and public welfare domains. Not all needs can be addressed by treatment and associated social services, and therefore it is important to identify those that can be addressed. This is a process of negotiation between the patient, the service provider(s), and usually the family.

Figure 3 provides a simplified schema of this process and highlights the utility of assessing "baseline outcomes" or needs from both the patient's and the service provider's perspectives. The perspective of the family and other stakeholders could be added to this, but for the sake of illustration, we will deal only with 2 perspectives, that of the patient and that of the care provider. At this simplified level, the patient and care provider can agree that a need does or does not exist (lower right box and upper left box, respectively). The latter situation indicates agreement that no action in a particular domain is needed. In the former situation, a plan needs to be formulated to address the need. To do this, the goal for addressing the need must be discussed in order to take action. For example, if unhappiness due to unemployment is a problem to be addressed, then the goal of an intervention needs to be discussed and agreed upon. Goals could include attainment of a certain type and level of employment or acceptance that level of disability precludes employment. These alternative goals imply quite different plans of action, and therefore agreement on the goal is needed before action is taken. The off-diagonals in this figure represent disagreements between the patient and the care provider on the existence of a problem. For example, the care provider may consider the patient's current housing situation inadequate, whereas the patient may be satisfied with it. Such a situation requires negotiation between the 2 to arrive at agreement. It is unlikely that an intervention to address a problem will be successful if both parties do not agree that a problem exists.

Some work has been reported on this approach. Malm and colleagues²⁸ used a quality-of-life assessment to guide treatment planning in a mental health clinic. Diamond²⁹ and Awad⁹ have discussed the use of quality-of-life assessment in the context of psychopharmacology for patients with chronic mental illness, in particular to enhance comfort and compliance. Liberman³⁰ has proposed that, in a rehabilitation context, quality-of-life assessments can be used to identify those life areas with which a patient is most dissatisfied and which therefore may be most fruitful to ad-

Figure 3. Negotiating Service Goals

		Observed Need (Provider Perspective)	
		No	Yes
Perceived Need (Patient Perspective)	No	No change in service	Negotiate
	Yes	Negotiate	Service need → Action

dress in a behavioral treatment program. Finally, Oliver in Great Britain has used quality-of-life assessments in developing and assessing a reformed national health policy mandating case management services.³¹

Ongoing Monitoring of Outcomes

This initial needs assessment and goal establishment sets the stage for ongoing monitoring of both proximal and distal outcomes. This monitoring permits the measure of desired and expected outcomes as well as the opportunity to detect unintended effects. For example, antipsychotic therapy may have the desired effect of reducing psychotic symptoms and permitting the patient greater access to employment opportunities. The unintended effect may be increased stress related to raised expectations by the patient and the family about work. The latter, if left unaddressed, could lead to clinical deterioration. To address this new opportunity effectively, vocational rehabilitation services are needed.

Assessing and monitoring these distal outcomes can also identify problems that may complicate clinical interventions and outcomes. For example, knowledge that a patient is experiencing considerable financial stress or facing possible housing eviction could be used to avert a social crisis that otherwise could lead to poor treatment compliance and clinical relapse. This "holistic" approach to the patient is much more gratifying to the patient and family and represents the type of humane treatment to which most clinicians aspire.

Using Outcomes Information to Adjust Treatment Plans

Despite our wealth of scientific knowledge about what can be helpful to people with schizophrenia, treatment ultimately occurs individually, one patient at a time. Research tells us what is likely to work on average, but it is essential to utilize ongoing information about outcomes for a specific patient in order to optimize care for that individual and to make the treatment truly "consumer-oriented."

For outcomes assessment to be worthwhile, it is essential that it be fed back to assist in ongoing care. This is often the Achilles' heel of outcomes management in that this feedback often does not occur and therefore, the value of outcomes data to clinicians is minimal. The challenges of providing this type of feedback are beyond the scope of this article, but clearly they are substantial and need to be addressed.

Outcomes Management at the Service System Level

Outcomes assessments can prove useful when assessing needs, developing intervention strategies, and evaluating outcomes of interventions at the system level. The development of services and the deployment of resources must be derived from a clear understanding of the needs of those being served and the priorities of these needs. Regarding system planning for persons with chronic mental illnesses, outcomes assessments provide important information about how patients are experiencing their current life circumstances (not just their health status) and permit some estimation about the priorities that they place upon these needs. Such information may be vital for allocating resources within service systems based upon patients' priorities. Although the ultimate allocation of resources must take into account the needs and perceptions of multiple constituencies (e.g., families, providers, and communities), patient-based outcomes assessments provide the opportunity for systematic input from service recipients who often lack access to this decision-making process. Also at the system level, outcomes assessment can provide ongoing feedback from these recipients about the impact of services and thus influence the further development of services and resource allocation. Monitoring of proximal and distal outcomes can be built into quality improvement programs. For example, such an outcomes monitoring program would track not only clinical outcomes, but also rates of involvement in vocational services, employment status, homelessness, and life satisfaction. It is not too fanciful to foresee provider "report cards" that include these distal outcomes.

Disclosure of off-label usage: The author of this article has determined that, to the best of his knowledge, no investigational information about pharmaceutical agents has been presented herein that is outside Food and Drug Administration–approved labeling.

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