

Assessment of Quality-of-Life Outcomes in Schizophrenic Patients

An interview with Anthony F. Lehman, MD, MSPH, Professor of Psychiatry and Director of the Center for Mental Health Services Research at the University of Maryland



Anthony F. Lehman, MD, MSPH

During his 20-year career, Dr. Lehman's clinical, teaching, and research activities have focused on serving people with severe and persistent mental illnesses. In particular, he continues to develop and assess quality-of-life outcome measures, evaluate innovative treatment programs for the homeless and people with psychiatric disabilities, and study the quality of care for people with schizophrenia.

Dr. Lehman has authored numerous scientific articles and coauthored 2 books dealing with families of, and comorbid substance abuse disorders in, the mentally ill. He is also currently the Principal Investigator for the Schizophrenia Patient Outcomes Research Team (PORT), as well as other state and federally funded research programs assessing outcomes and employment for people with mental illness.

Quantifying and Validating Functional Outcomes

AJMC: *You have been involved in quality-of-life research for approximately 20 years. What prompted you to look beyond clinical outcomes and try to quantify functional outcomes?*

Dr. Lehman: It was really based on my clinical work with patients. I can give 2 case examples that helped prompt me to expand my focus. The first case was a patient I treated when I was an intern. At that time I ran a medication group, so I was mainly focusing on the medication issues: compliance and symptoms. The patient in this example was a woman with chronic schizophrenia, who was not showing up to the clinic for her appointments. A social worker and I went on a home visit and discovered this woman living in extreme squalor in a group home where she was being neglected. That particular case pointed out to me the importance of paying attention to things other than whether a person showed up for medications, such as a person's living situation.

In another case I had when I was a resident, there was a woman with chronic schizophrenia who had stopped taking her medicine and was admitted to the hospital, acutely ill. She was started back on her antipsy-

chotic drug and did well. She was approaching discharge, and the other doctors and I felt her current housing situation, which was a board care home in the inner city of Los Angeles, was not very good. We did not talk to her much about it but decided a change in housing situation would be good for her, and we found her a very nice place to live near the ocean. We probably extended her hospital stay for a couple of weeks to do that. We later learned that she went back to her old place when she was discharged because that was where her friends were. That was where she wanted to be.

Those kinds of experiences led me to feel like we needed to pay much more attention to not only functional status but also patient preferences and other aspects of a person's life to offer them the best care.

I believe, and probably many psychiatrists would agree, that you can focus on the narrow part of what happens in the office, such as the symptoms, but the most important things in a person's life may be eviction from his or her residence, having conflicts in personal relationships, or not having enough money. Those kinds of situations can dramatically affect a person's well-being and can also directly affect levels of symptoms and ability to comply with treatment. A psychiatrist has to have a whole picture of the person in order to provide care.

AJMC: *We have discussed clinical outcomes and functional outcomes, such as rehabilitation and employment abilities. How do you categorize the more ambiguous quality-of-life criteria, such as life satisfaction, attitude towards medication, and access to housing?*

Dr. Lehman: Those constitute what has been called the humanitarian domain, as opposed to the rehabilitative domain, which is really function-

al status. The humanitarian domain is a more subjective experience: how patients have been feeling about their life, and, in a narrower way, how they have been feeling about their medication. Although these are softer outcomes and sometimes harder to measure, most people would probably say that what is most important to them is how they feel about their lives, not how much money they make or how big their house is.

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AJMC: *What is the role of quality-of-life measurements in an efficacy study or clinical trial?*

Dr. Lehman: In short-term clinical trials, life satisfaction measures are not necessarily needed. To the extent that levels of symptoms and side effects influence how someone is feeling, short-term clinical trials might capture most of the variance. If one looks at broader, longer-term clinical trials, or clinical trials that combine different types of treatments, for example, medication and a psychosocial treatment, then these quality-of-life outcomes become more important.

And if the quality of life in a clinical trial is going to be measured, it is important to include a patient self-report measure.

AJMC: *We are seeing increasing numbers of studies attempting to validate the patient self-reported measurements of quality of life. What are some of the barriers to objective self-reporting by schizophrenic patients?*

Dr. Lehman: Certain kinds of symptoms, primarily depression, will affect reports of life satisfaction, including in people with schizophrenia, who experience severe distortions of reality and more acute psychosis. These conditions raise serious questions about the validity of those reports. Beyond that, for stable patients who are not highly symptomatic, these reports work pretty well. The problem is the patient's perspective on outcomes may not agree or is not weighted in the same way as a clinician's perspective—much like those case studies I mentioned earlier. I do not think it is a validity problem as much as it is the need for openness to really hear how patients feel about things. If for no other reason, it can be useful in making treatments credible to patients. They need to feel that whoever is providing the treatment is willing to listen to their point of view.

My theory is a treatment that attends more to quality-of-life issues will result in better treatment compliance and would probably result in better outcomes, although I do not have any data to prove this at this point. The failure to really listen to patients often creates problems in the process of care, which can have all kinds of other effects. Sometimes the treatment we provide has some unintended side effects on other aspects of patients' lives that we need to know about to keep the treatment going in the right direction.

AJMC: *Studies have shown that temperament affects a patient's reported quality of life or life satisfaction. Is it possible to accurately measure quality of life in pessimistic patients?*

Dr. Lehman: People have different baselines, so it is important to look at changes over time rather than comparing directly with another person. For example, my normal rating of life satisfaction may be 3 because I am a pessimist, and someone else's normal rating may be 5 because he or she is an optimist. If both of us underwent the same treatment, my score might go up to 4, and the other person's score would go up to 6. We have each had the same amount of change so the treatment has added a certain value to our lives, but the rating is different for me than for the other person. What is informative is the change, rather than the absolute score. When we are doing quality-of-life studies, we have to have some measure of depression in order to adjust for that kind of difference across people.

AJMC: *How critical is the family's or caregiver's perceived change in the patient's quality of life? Should their observations be included in quality-of-life measurements?*

Dr. Lehman: I think it is important to get the family's perspective on whether things have gotten better or not. Particularly if the patient lives at home, families often have a perspective that is important to take into account. Again, it is sometimes different from the patient's and the practitioner's perspectives.

In psychotherapy research, there is a tradition to look at a tripartite view of outcomes by Hans Strupp.¹ He argued that to measure outcomes in psychotherapy (ie, nonschizophrenic patients), a clinician should look at the patient's, therapist's, and significant

other's (generally the spouse's) perspectives. In terms of trying to assess the impact of therapy, one should always get those 3 perspectives.

Now, these 3 perspectives do not always agree. Hans Strupp's argument is not that one is more valid than the other, but that they provide alternative viewpoints. This idea is valuable in terms of ongoing treatment adjustment. For example, it is important to know if the therapist and the family feel like things are getting better, and the patient does not. However, those opposing perspectives do not mean that the patient is wrong. Similarly, if the patient and therapist feel like things are getting better, and the spouse does not, a doctor would want to pay attention to that. In schizophrenia, knowing the family's, the patient's, and the therapist's perspectives gives doctors a much richer sense of what they are accomplishing.

AJMC: *What are the proximal and distal outcomes when measuring the effectiveness of antipsychotic agents versus vocational rehabilitation? What happens to this relationship when you measure proximal and distal outcomes with combined treatments?*

Dr. Lehman: The proximal outcomes of the treatment are the outcomes you would expect to see changed in the shortest period of time or to which the intervention is most directly targeted. For a medication, that would usually be the symptoms of schizophrenia and side effects of that medication. The more distal outcomes might be improvement in functional status and improvement in quality of life. For vocational rehabilitation, the proximal outcomes would be improvement in vocational functioning, which in turn might lead to a distal outcome of improvement in symptoms. Another proximal outcome of vocational intervention is improvement in income.

With combined treatment—where you are combining medication and rehabilitation—the proximal outcomes would include both the proximal outcomes for the medication and vocational rehabilitation. And the advantage is that you are taking more direct action to improve more outcomes at the same time, such as reducing symptoms and improving functioning.

AJMC: *What is the relationship between the proximal outcomes of psychopathology and employment status?*

Dr. Lehman: In schizophrenia, the data suggest the symptoms most directly related to improvement in functional status, that is, the proximal outcomes, are the negative symptoms: loss of motivation, lack of interest in interpersonal relations, and depression. These types of impairments really have a negative impact on a person's ability to work. Presumably, any treatment that improves those symptoms will probably result in improvement in some functional outcomes. The positive symptoms are also related to functional status, but they are not as strongly related as the negative symptoms. There is evidence that treatments that improve proximal clinical outcomes will enhance more distal functional outcomes.

AJMC: *How does the severity or chronicity of the illness affect quality-of-life measurements?*

Dr. Lehman: If a person is severely symptomatic, it impairs his or her ability to report on quality of life. This is also true for people who are very depressed—it distorts their quality-of-life report. You either have to adjust for it statistically or take it into account some other way. Other than

that, we have done quality-of-life measurements with large numbers of people with chronic schizophrenia, and the reliability and validity studies have looked quite good.²

The definition of a quality-of-life assessment needs to be broader in a chronically ill patient, because the services are attending to a broader range of problems. The example I would give is regarding people who have been doing just fine in their life and then become acutely depressed. They would be treated for their severe depression. The goal is really to get them back to how they were just before they became ill. They are probably going back to work, back to their families, doing all of the things they were doing before. You try to get them over the acute symptoms so the outcomes measures can be fairly narrow focusing on the clinical outcomes.

If you have patients who are chronically disabled, and they have problems in multiple areas of their lives, then often what doctors are trying to do is help them recover over a long period of time as much as they are able to. This is not just in terms of clinical outcomes, but also patients' quality of life, their relationships with others, and so on. And historically, the treatment system has taken more responsibility for helping people who are chronically ill find housing, have some kind of meaningful activity during the daytime, and so on. Those outcomes need to be measured as a way of holding ourselves accountable to the notion that in treating the severely mentally ill, we are treating more than just the symptoms.

AJMC: Recent studies have examined the relationship between symptoms and quality of life. What effect on quality of life have you observed with the newer atypical agents with regard to symptom improvement?

Dr. Lehman: I think these agents are particularly important for someone who is having the onset of schizophrenia. Drugs that have fewer side effects and have more of an antidepressant effect may allow the patient to regain some of the functions lost in the early stages of the illness. This may allow someone to stay in school or stay in the work force, which in itself has a snowball effect on the patient's life. I am hopeful that the newer drugs will have more impact on those other areas of people's lives as well as the symptoms.

The Future of Functional Outcomes in Treatment Decisions

AJMC: To what extent does the "awakenings" phenomenon or degree of insight seen with the newer atypical agents affect quality-of-life measurements?

Dr. Lehman: The awakenings phenomenon can cut both ways in quality of life. On the one hand, a doctor may have some patients who might suddenly be feeling a lot better, because they are doing a lot better clinically, and that would probably improve how they are feeling about themselves and about their life. It would give them new hope.

On the other hand, a patient may experience an awakening and realize he or she has lost 15 years of productive life. It can lead to depression. There certainly have been case reports where people have committed suicide with an awakening. In those cases, the awakening has made them acutely aware of the devastation that the illness has had in their lives. Now, that does not mean they should not be treated. It is important to pay attention to the psychological and social implications when someone does have a dramatic clinical improvement. Doctors should be prepared to offer them

therapy and rehabilitation services that can help them cope with their newfound abilities.

It really points to the importance of combined treatment for these patients. Waking up is not enough; a patient has to have something to do. I think we have responsibilities in helping people now find what it is they want to do in their lives.

AJMC: As the focus in clinical studies changes to reflect quality-of-life issues (distal outcomes), to what extent are managed care organizations held accountable for functional outcomes?

Dr. Lehman: The implication in measuring any outcome is that it is an important outcome, and one expects it to be affected by intervention. There is no point in measuring an outcome that is not part of the theory about why or how a treatment works. For example, if a medication does not affect quality of life, this outcome would not be measured, because no claims are made that medication affects quality of life. When we start to make claims that quality of life is improved, then there is an obligation to measure it.

When deciding which outcomes to monitor in the managed care context, I think the choice becomes even more important because there is an implication that quality of life is an outcome to which practitioners are going to be held accountable. There is the expectation that the practitioner or the healthcare system is going to improve quality of life.

When doctors are treating an acute illness, it is not routinely expected of them to help people find a better house to live or a spouse, or get more friends. Measuring those as outcomes is not fair; doctors should continue to look at clinical outcomes.

With the chronically ill, state mental health systems have historically

been expected to house people, to provide rehabilitation, and so on. So as the responsibility for the severely mentally ill gets folded into managed care systems, I think it is very important to maintain a focus on those types of outcomes as well. Otherwise, you are saying to the medical system: you only have to treat the symptoms, and the fact that people are becoming homeless or not being rehabilitated is

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not your responsibility. It is not clear whose responsibility it is in society to help these people.

Wherever the responsibility falls, the funding has to go with it. I think that is a real dilemma. From a healthcare provider standpoint, that is, working with a set amount of money, the advantage is to have the outcomes be defined as narrowly as possible. And from a societal standpoint, or maybe from a patient or family standpoint, it is desirable to get a broader range of assistance. That produces some tension.

AJMC: Studies have shown that newer atypical agents improve quality of life, yet are more expensive than typical agents. Knowing that physicians may have to work with

determined budgets, do you believe that managed care should look at total costs before making decisions for or against a new, more expensive drug?

Dr. Lehman: The short answer to that is yes. The pharmacy costs are higher for some of these new drugs, so you have to look at total costs, direct and indirect. There might be cost savings realized through a reduction in hospitalization, which offsets the cost of the medication.

In other medical conditions, if there is another medication available, we do not really talk about not allowing people to get access to it. And sometimes as technology for a condition improves, costs do go up. As a society, we have been willing to pay that in other areas of medicine (transplants, neonatal care, fertility care).

It has to be fair. We should extend the same thing to people with schizophrenia. It is not adequate to just say that we cannot spend any more money than we do. But we have to spend it on things that are worth spending it on.

AJMC: *Are patient-reported quality-of-life measurements sufficiently reliable in general psychotic patient populations to be included in cost-effectiveness studies?*

Dr. Lehman: I think they are. However, I would not use them as the only measure of effectiveness, but I think they are a valid measure—one valid measure of effectiveness.

AJMC: *Studies have shown that supportive families who are educated about the disease can reduce clinical relapse in patients. To what extent has family education been incorporated into the treatment of psychosis?*

Dr. Lehman: Not enough. In our survey, we found that even with the most

liberal definition of family education (where families reported that someone had talked to them about the diagnosis and the treatment) only about 30% of families had received education.³⁻⁵ All of the recommendations that have been coming out [from the American Psychiatric Association] on the treatment of schizophrenia have said that a basic component of good practice is to provide the family with education and support. It is probably a very cost-effective program.

AJMC: *Based on your experience with the Patient Outcomes Research Team (PORT), are schizophrenic patients more interested in alleviating the clinical symptoms or improving their functional/quality-of-life status, such as work capabilities and opportunities, social relationships, and life satisfaction?*

Dr. Lehman: Most patients' concerns relate to quality-of-life issues, the other ways that their lives are affected. Those outcomes are, in most patient surveys, much more important than reducing symptoms. It is not that a reduction in symptoms is not important to patients; they certainly will report symptoms and side effects, but most of what they talk about are other problems in their lives.

AJMC: *Will increased patient interest in functional outcomes affect future clinical trial design and treatment decisions? Will the outcomes emphasis shift away from clinical measurements when functional status is more important to the patient?*

Dr. Lehman: I think the shift is already happening. I do think that what doctors are trying to accomplish in a medication trial is fairly narrow. They are evaluating the clinical

impact of the medication. In that sense, I do not know that a quality-of-life measure adds much. If there is a particular hypothesis that says that a newer medication, for example, improves quality-of-life outcomes beyond the reduction in symptoms and side effects, then it is important to measure those, that is for clinical trials. If you move into clinical care, then you are not just trying to improve symptoms. You are actually trying to improve somebody's well-being, so the quality-of-life measures are more important in that context.

AJMC: What role have consumer advocacy groups played in the shift to include functional status/quality-of-life outcomes in clinical studies?

Dr. Lehman: I think they have played a major role because what you hear from consumers and from families is that the most important thing is to help the person get on with his or her life (relating to functional status/quality-of-life issues). A 20% reduction in a Brief Psychiatric Rating Scale [BPRS] score does not mean a whole lot to them, even though it might be the gold standard of outcomes in a

clinical trial. Consumer advocacy groups have had a very strong voice. They have said "What we want is something that is relevant to our lives." I think they have played a major role in this shift and will continue to demand services and improved quality of life.

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