Communication of Potential Benefits and Harm to Patients and Payers in Psychiatry: A Review and Commentary

Renrong Wu, MD, PhD[1,2]; David E. Kemp, MD, MS[1]; Martha Sajatovic, MD[1]; Jingping Zhao, MD, PhD[2]; Joseph R. Calabrese, MD[1]; and Keming Gao, MD, PhD[1]

[1]Department of Psychiatry, Mood and Anxiety Clinic in Mood Disorders Program, Case Western Reserve University School of Medicine, University Hospitals Case Medical Center, Cleveland, Ohio; and [2]Institute of Mental Health of the Second Xiangya Hospital, Central South University, Changsha, Hunan, China

ABSTRACT

Background: Communicating potential benefits and harm to patients and payers is essential for high-quality care. However, there are no published guidelines or consensuses on how to communicate potential benefits and harm to patients and payers.

Objective: The goal of this review was to identify key elements for communication between clinicians, patients, and payers to achieve maximal benefits and minimal risk.

Methods: Literature published from January 1980 to July 2011 and cited on MEDLINE was searched using the terms *communication, benefit, harm, effectiveness, cost, cost-effectiveness, psychiatry, bipolar disorder, schizophrenia,* and *major depressive disorder*. Elements related to communicating benefits and/or harm to patients and payers were identified, with only key elements discussed in detail here.

Results: Evidence-based medicine, number needed to treat to benefit (NNTB) or harm (NNTH), and the likelihood of being helped or harmed (LHH) have been advocated as the basis for communication in all specialties of medicine. Phase-dependent communication of benefits and harm is novel, especially in patients with different phases of illness, such as bipolar disorder. Duration-dependent (short-term versus long-term) communication is essential for all psychiatric disorders to reduce the burden of relapse and adverse events with long-term treatment. For drugs with multiple therapeutic indications, a disease-dependent approach is crucial to maximize benefits and minimize harm. The exclusion of comorbid psychiatric disorders in pivotal efficacy trials affects their generalizability. Communicating cost (direct versus indirect) is an essential component in reducing health care expenditures. The results of available cost-effectiveness analyses of psychiatric pharmacotherapy have been inconsistent and/or contradictory.

Conclusions: Evidence-based communication of potential benefits and harm to patients and payers, using NNTB, NNTH, and LHH, should be the key principle that guides decision making. Phase-, duration-, and disease-dependent communication and evidence-based cost-saving principles can maximize benefit and reduce harm. (*Clin Ther*. 2011;33:B62–B76)

Key words: benefit, communication, comorbidity, cost-effectiveness, harm, number needed to treat.

INTRODUCTION

Like other specialties of medicine, in psychiatry, communication between health care professionals and patients and payers is essential for high-quality care. Unlike other specialties of medicine, in psychiatry, patients may carry a stigma that may sometimes cause them to be unwilling to receive proper treatment and/or to continue receiving treatment once they become asymptomatic. Psychiatric disorders such as schizophrenia, bipolar disorder, treatment-refractory major depressive disorder (MDD), and some anxiety disorders may be chronic and recurrent. Without maintenance treatment, relapse of these chronic illnesses may be inevitable.[1–9] The consequences of relapse may increase the burden on not only patients' health but also society.[10–12]

Disparity of health coverage for patients with psychiatric illness remains a worldwide problem. Restrictions on accessing certain medications or services imposed by payers are common. Consequently, patients with psychiatric illness may be unable to receive proper

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treatment or may be required to making unnecessary changes. Subsequently, the risk for nonadherence and relapse and their ensuing costs may increase.[11,13,14]

Clearly, it is essential to communicate the potential benefit versus harm to patients and payers of each intervention or policy to provide the best care for each patient. Although communication with patients is a basic component of training for every health care professional, there are no published guidelines or consensuses on how to communicate effectively with patients and payers, especially with reference to communication of potential benefits and harm. Undoubtedly, improved communication may help patients to comply with their treatment and to secure needed resources. This article proposes some key elements to help clinicians to communicate with patients and payers.

METHODS

Literature published from January 1980 to July 2011 and cited on MEDLINE was searched using the terms *communication, benefit, harm, effectiveness, cost, cost-effectiveness, psychiatry, bipolar disorder, schizophrenia,* and *major depressive disorder*. Elements related to communicating benefits and/or harm to patients and payers were identified, with only key elements discussed in detail here.

RESULTS

Communication of Evidence-Based Medicine

A MEDLINE search with different combinations of key words uncovered more than one thousand abstracts, 105 articles were carefully examined and included for this review. Clinical experience is important in patient care, but evidence-based practice and good communication with patients and payers is essential for providing the best care for patients. *Evidence-based medicine* is defined as the integration of clinical expertise and the best external evidence,[15] with the key being "best" evidence. Even now, it is difficult to define what constitutes "best" evidence. Randomized, controlled trials, especially double-blind trials, were long believed to provide the best evidence, but researchers have now attempted to grade the quality of evidence using classification systems.[15] The Grading of Recommendation Assessment Development and Evaluation Working Group has emphasized the importance of grading the quality of evidence among randomized controlled trials.[16,17]

Findings from systematic reviews and meta-analyses based on randomized controlled trials have also been proposed as the best evidence, followed by randomized controlled trials.[16,17] However, systematic reviews and meta-analyses commonly lag behind randomized controlled trials and other sources of new scientific discoveries. It is important for clinicians and payers to have their own updated best evidence–based information. A detailed discussion on how to find evidence-based information is beyond the scope of this review. A step-by-step strategy for identifying evidence-based information has been proposed.[18]

Communication of Efficacy

Conventional Efficacy Measures

Although the data from randomized, double-blinded, controlled trials may provide the best evidence, they rarely can directly be used to communicate with patients or payers. Commonly, the efficacy and tolerability of a psychotropic drug are determined through randomized, double-blind, placebo-controlled trials, with efficacy measured through standardized rating scales, such as the Hamilton Depression Rating Scale (HDRS) or the Montgomery-Åsberg Depression Rating Scale (MADRS) for depression, the Young Mania Rating Scale (YMRS) for mania, and the Positive and Negative Syndrome Scale (PANSS) for psychosis. For maintenance studies, the primary outcomes are commonly the difference in time to relapse/intervention between studied treatments and their controls.[19]

Overall changes in rating scales have little use in clinical practice and policy making. First, the use of rating scales to measure symptom severity has not been routinely evaluated in clinical care settings, although they can provide useful information. Second, it is often difficult for patients to understand the meaning of, for example, a 20-point reduction on the HDRS or a 15-point reduction on the YMRS. Third, the rate of response (eg, $\geq$50% reduction in depression symptoms or manic symptoms, $\geq$30% reduction in psychotic symptoms in schizophrenia), a commonly used secondary outcome, also has limited clinical relevance. For instance, if a patient has a MADRS total score of 40 points at baseline and that score is reduced to 20 points at the end of study, the patient will meet the criteria for response. However, a MADRS total score of 20 points suggests that the patient is still moderately depressed. Without interpreting scores in the appropriate context, it may be difficult for payers to understand the meaning of these changes. Therefore, it is important for clini-