



ELSEVIER

Contents lists available at [SciVerse ScienceDirect](http://www.sciencedirect.com)

## Psychiatry Research

journal homepage: [www.elsevier.com/locate/psychres](http://www.elsevier.com/locate/psychres)

## The Patient Assessment Questionnaire: Initial validation of a measure of treatment effectiveness for patients with schizophrenia and schizoaffective disorder

Ramin Mojtabai<sup>a</sup>, Patricia K. Corey-Lisle<sup>b</sup>, Edward Hak-Sing Ip<sup>c</sup>, Irina Kopeykina<sup>d</sup>, Sophia Haeri<sup>e</sup>, Lisa Janet Cohen<sup>d,\*</sup>, Sally Shumaker<sup>f</sup>

<sup>a</sup> Johns Hopkins University, School of Public Health, Mental Health Department, Baltimore, MD, USA

<sup>b</sup> Amgen, Thousand Oaks, CA, USA

<sup>c</sup> Wake Forest University School of Medicine, Department of Biostatistical Sciences, Winston-Salem, NC, USA

<sup>d</sup> Beth Israel Medical Center, Department of Psychiatry, NY, USA

<sup>e</sup> The New School, Department of Psychology, NY, USA

<sup>f</sup> Wake Forest University School of Medicine, Department of Social Science and Health Policy, Winston-Salem, NC, USA

### ARTICLE INFO

#### Article history:

Received 22 August 2011

Received in revised form

6 June 2012

Accepted 10 June 2012

#### Keywords:

Test construction

Self-report instrument

Measurement

Treatment response

Schizophrenia

Treatment effectiveness

Treatment efficacy

### ABSTRACT

Investigation of patients' subjective perspective regarding the effectiveness – as opposed to efficacy – of antipsychotic medication has been hampered by a relative shortage of self-report measures of global clinical outcome. This paper presents data supporting the feasibility, inter-item consistency, and construct validity of the Patient Assessment Questionnaire (PAQ)—a self-report measure of psychiatric symptoms, medication side effects and general wellbeing, ultimately intended to assess effectiveness of interventions for schizophrenia-spectrum patients. The original 53-item instrument was developed by a multidisciplinary team which utilized brainstorming sessions for item generation and content analysis, patient focus groups, and expert panel reviews. This instrument and additional validation measures were administered, via Audio Computer-Assisted Self-Interviewing (ACASI), to 300 stable, medicated outpatients diagnosed with schizophrenia or schizoaffective disorder. Item elimination was based on psychometric properties and Item-Response Theory information functions and characteristic curves. Exploratory factor analysis of the resulting 40-item scale yielded a five factor solution. The five subscales (General Distress, Side Effects, Psychotic Symptoms, Cognitive Symptoms, Sleep) showed robust convergent ( $\beta$ 's=0.34–0.75, average  $\beta$ =0.49) and discriminant validity. The PAQ demonstrates feasibility, reliability, and construct validity as a self-report measure of multiple domains pertinent to effectiveness. Future research needs to establish the PAQ's sensitivity to change.

© 2012 Elsevier Ireland Ltd. All rights reserved.

### 1. Introduction

Despite early enthusiasm about the benefits of second-generation antipsychotics (SGAs) medications over older first-generation antipsychotics (FGAs), recent multi-site comparative trials of antipsychotic therapy effectiveness have failed to demonstrate meaningful differences in effectiveness between these treatments (Lieberman, 2006; Lieberman et al., 2005). According to the findings of two well-known and publicly-funded clinical studies (CATIE and CUTLASS), the two generations of antipsychotic drugs appear to be similar with regard to efficacy for psychosis, tolerability, and treatment compliance in schizophrenic patients

(Jones et al., 2006; Carpenter and Buchanan, 2008; Lieberman et al., 2005). On the other hand, a multitude of recent studies, including the CATIE study, have consistently shown that FGAs and SGAs have distinct adverse side-effects profiles. It appears that while FGAs are associated more frequently with extrapyramidal side-effects, patients taking SGAs are at a higher risk of significant weight gain and metabolic disturbances (Kelly et al., 2008; Carpenter and Buchanan, 2008; Opjordsmoen et al., 2009). The implications of these distinct side-effect profiles for continuation of treatment and patient adherence highlights the importance of assessing not only the efficacy but also the effectiveness of the medication prescribed to schizophrenic patients in usual treatment settings. While efficacy assesses how well a drug treatment is working to alleviate symptoms in the context of a clinical trial, effectiveness studies evaluate the impact of treatments on health outcomes under conditions that approximate routine care (Gabbard et al., 1997). Assessments of effectiveness

\* Correspondence to: Beth Israel Medical Center, 1st Avenue and 16th Street, New York, NY 10003, USA. Tel.: +1 212 420 2316; fax: +212 844 7659.

E-mail address: LCohen@chpnet.org (L.J. Cohen).

typically involve a simultaneous evaluation of the trade-offs between efficacy, safety, and tolerability in the context of routine care (Collaborative Working Group on Clinical Trial Evaluations, 1998). To be able to accurately evaluate the risks and benefits of available treatment options and to choose the optimal medication regimen for patients with schizophrenia, clinicians need to know about differences in effectiveness of antipsychotic medications. To this end, it is critical to have appropriate psychiatric measures to assess the effectiveness of psychotropic drugs in treatment of schizophrenia.

Standard instruments used in the assessments of clinical outcome in patients with schizophrenia, such as the Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987), and Scale for the Assessment of Positive Symptoms (SAPS) and Scale for the Assessment of Negative Symptoms (SANS) (Andreasen and Olsen, 1982), provide valuable information regarding symptoms and clinical outcome. However, these assessments are rated by clinicians and reflect their perspectives. Thus, they may not accurately reflect benefits and/or disadvantages of treatments as perceived by the patients. Such a subjective assessment is critical as patients' experience of their medication as intolerable and/or ineffective remains a primary cause of poor medication adherence and/or discontinuation (Lieberman et al., 2005).

Given the centrality of treatment adherence to clinical outcome, there has been increased interest in instruments assessing patients' own perspective of treatment in recent years. These measures show that it is possible to reliably and validly assess schizophrenic patients' subjective experience of clinical phenomena (Hellewell, 2002; Vothknecht et al., 2011) and that such measures are associated with both adherence and clinical outcome (Naber et al., 2001). Moreover, measures of subjective wellbeing have been able to differentiate medication classes (Voruganti et al., 2000; Hellewell, 2002). Many such measures, however, focus on specific domains of treatment and are not designed to simultaneously assess different aspects of treatment effectiveness in schizophrenia spectrum disorders from the patient perspective. For example, the Schizophrenia Outcomes Module (SCHIZOM) (Cuffel et al., 1997) mainly captures the symptoms of the illness and does not target issues of tolerability and safety. The Drug Attitudes Inventory (DAI) (Hogan et al., 1983) provides a measure of the overall valence (positive or negative) of subjects' feelings about their medications but does not address symptom reduction. Likewise, the Subjects' Response to Antipsychotics Questionnaire (SRA) covers a wide range of side effects associated with anti-psychotic treatment but does not assess psychopathology (Wolters et al., 2006). Other self-report measures of health outcomes target the domains of health-related quality of life (Derogatis and Melisaratos, 1983; Cuffel et al., 1997; Collaborative Working Group on Clinical Trial Evaluations, 1998; Collins et al., 1999; Dassori et al., 2003; Chinman et al., 2004), functioning (Endicott et al., 1993; Lehman et al., 2003), symptom-associated distress (Derogatis and Melisaratos, 1983), and treatment satisfaction (Collins et al., 1999; Gray et al., 2005; Rofail et al., 2005).

Several self-report measures explicitly address effectiveness and cover a broad array of treatment-relevant domains. The Subjective Wellbeing under Neuroleptic Treatment (SWN) (Naber et al., 2001; Vothknecht et al., 2011) is a 20-item self-report questionnaire with five subscales and a total scale. The subscales measure mental, social, emotional, and physical functioning and self-control. The Personal Evaluation of Transitions in Treatment (PETIT) is a 30-item scale that yields a single total score encompassing the following domains: psychological wellbeing, mood, energy level and activities, biological functions, self-esteem, coping abilities, cognition, communication, stigma, social functioning, aptitude towards productivity, and attitudes

towards medication (Voruganti and Awad, 2002). Nonetheless, these instruments primarily address the "distal effectiveness" of antipsychotic treatment as it manifests in patients' general functioning in the world (Voruganti and Awad, 2002). Thus they do not target immediate indicators of effectiveness, such as symptom severity, side effects and general tolerability or safety—issues of critical concern in clinical trials.

In sum, although a number of instruments address treatment outcome from the patient's perspective, there remains significant need for a brief, self-report instrument that specifically targets effectiveness, incorporating measures of efficacy (i.e., symptom reduction), side effects and other domains related to tolerability and safety. As a compliment to clinician-rated assessments, such an instrument may enhance our ability to differentiate real world treatment impacts between antipsychotic agents and help illuminate patients' needs in the development of future antipsychotic medications.

In this paper we describe the development of an instrument specifically designed to provide a broad measure of subjective experience of medication treatment effectiveness in patients with schizophrenia spectrum disorders. Although ultimately effectiveness reflects change in patient functioning over time in response to treatment, this research serves as a necessary first step in the instrument development process. Here we demonstrate the psychometric validity of our instrument as a broad measure of psychiatric symptoms, medication side effects and general well-being. Specifically, we provide data on the feasibility, internal consistency and construct validity of our measure. Construct validity was derived both from factor analysis and from regression analyses with self-report measures of related constructs.

## 2. Methods

### 2.1. Subject recruitment

A total of 300 subjects diagnosed with either schizophrenia or schizoaffective disorder by DSM-IV-TR criteria participated in this study and completed the assessment. Participants were recruited through consecutive referrals from the psychiatric outpatient services at two hospitals located in New York City. Referrals were obtained by contacting hospital clinicians to inquire if any of their patients were interested in participating in the study. The study was also introduced to patients via periodic presentations at patients' weekly group meetings and flyers detailing the study distributed in the waiting rooms at the recruitment sites.

Inclusion Criteria included confirmed diagnosis of schizophrenia or schizoaffective disorder by chart and clinician, capacity to consent to participate in research, and ability to understand spoken and written English. Exclusion criteria included severe cognitive deficit, organic brain syndrome (e.g., delirium, dementia, substance intoxication), florid psychosis, and immediate risk to self or others.

Written consent was obtained prior to the beginning of the interview. The study was approved by the Institutional Review Boards of the participating institutions.

### 2.2. Development of the Patient Assessment Questionnaire (PAQ)

The PAQ was developed by the scientific staff of Bristol-Myers Squibb in collaboration with Wake-Forest University School of Medicine. This preliminary instrument was developed using accepted instrument development techniques in alignment with FDA instrument development guidelines (US Department of Health and Human Services, 2006). The aim in developing the PAQ was to create an instrument to assess effectiveness of antipsychotic medication treatment from the unique perspective of the patient. To this end, the PAQ was designed to assess a global treatment effectiveness as defined by medication tolerability, safety, and efficacy. The measure also included items related to patients' quality of life as it pertains to their psychiatric condition and treatment.

Item development took place through an elaborate process conducted by a team of experts from different departments at Wake-Forest University in North Carolina. The team, which included experts in psychiatry, social and behavioral sciences, and psychometrics, conducted brainstorming sessions for item generation and content analysis, convened multiple focus groups with patients, and utilized expert panel reviews. The instrument also went through many iterations

متن کامل مقاله

دریافت فوری ←

**ISI**Articles

مرجع مقالات تخصصی ایران

- ✓ امکان دانلود نسخه تمام متن مقالات انگلیسی
- ✓ امکان دانلود نسخه ترجمه شده مقالات
- ✓ پذیرش سفارش ترجمه تخصصی
- ✓ امکان جستجو در آرشیو جامعی از صدها موضوع و هزاران مقاله
- ✓ امکان دانلود رایگان ۲ صفحه اول هر مقاله
- ✓ امکان پرداخت اینترنتی با کلیه کارت های عضو شتاب
- ✓ دانلود فوری مقاله پس از پرداخت آنلاین
- ✓ پشتیبانی کامل خرید با بهره مندی از سیستم هوشمند رهگیری سفارشات