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## A review of self-report medication side effect questionnaires for mental health patients



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### ABSTRACT

Side effects of psychotropic medications are important determinants of adherence to treatment. Discussion between the patient and clinician facilitated through the use of a side effect self-report questionnaire (SRQ) could lead to improved communications and treatment adherence. The aim of this review was to 1) identify all currently available side effect SRQs used in the assessment of mental health patients' subjective experiences, 2) evaluate the characteristics of the studies and 3) assess the psychometric properties of each of the questionnaires. Eight electronic databases were searched for peer-reviewed published articles. Six side effect SRQs were identified. Two independent reviewers assessed the quality of the study designs and psychometric properties of the identified SRQs. All questionnaires consisted of closed questions relating to antipsychotic side effects and completion times ranged from 5 to 20 min. Five questionnaires had undergone some form of psychometric testing, ranging from basic to comprehensive. There is a need in everyday clinical practice for a side effect communication tool applicable to all psychotropic medications, which allows the patient to express their subjective beliefs about their medications. This could provide an important contribution to the working relationship between patients and clinicians leading to informed decision-making and improved adherence.

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### 1. Introduction

The global burden of disease attributable to mental disorders exceeds that for all other medical conditions (Murray, 2012). Unlike some chronic diseases, these illnesses will frequently impact not only the patient, but also those in close contact with the patient and society at large. Treatment of mental disorders often involves the use of psychotropic medications (Happell et al., 2004; Wolters et al., 2009). In Australia in 2008–2009, 1 in 10 prescription claims was for psychotropics; they comprised mainly of antipsychotics (51%) and antidepressants (41%) (AIHW, 2010). Similarly both classes of drugs rank high in terms of sales and prescriptions dispensed in the United States in 2011 (Lindsley, 2012) with evidence of significant increase in polypharmacy in recent years involving these drugs (Castle et al., 2002; Mojtabai and Olfson, 2010).

A significant dilemma facing this patient group and their clinicians is the use of medications that on one hand will ameliorate

their symptoms but on the other hand will almost always result in debilitating and intolerable side effects (Gerlach and Larsen, 1999; Fakhoury et al., 2001; Castle et al., 2002; Farcas et al., 2010). The emergence of these side effects some of which include severe weight gain, impotence, insomnia, chronic sedation, lack of ability to concentrate and function in daily activities has been linked to very high rates (up to 90%) of patients discontinuing pharmacological treatment (Lieberman et al., 2005; Llorca, 2008; Goff et al., 2010).

Discontinuing treatment or non-adherence often leads to rehospitalization, relationship breakdown, loss of housing, loss of employment, involvement in substance abuse, crime and suicide (Ascher-Svanum et al., 2008; Yen et al., 2009; Chapman and Horne, 2013). This vicious cycle of illness, prescribed medication leading to intolerable side effects, non-adherence, discontinuation effects (which can mimic and be practically indistinguishable from illness relapse) (Cerovecki et al., 2013) and/or frank illness relapse is seen in a large number of mental health patients with serious consequences and who in the worse cases, take their own life (Naber and Karow, 2001; Llorca, 2008).

At the core of the problem is the means for effective communication between patients and clinicians (Gerlach and Larsen,

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1999; Naber and Karow, 2001; Happell et al., 2004). Psychiatrists have recognized this problem and there is an urgent need in clinical practice for an effective communication tool for patients to describe their subjective beliefs about the side effects of medications and their likelihood to alter or discontinue treatment (Cabeza et al., 2000; Dott et al., 2001; Dassori et al., 2003; Goff et al., 2010). Such a tool will give the clinician additional insight into the patient's experience with these medications and facilitate open dialogue with this group of patients, who as well, often have difficulty in effective communication in part due to poor or diminished cognitive ability (Dassori et al., 2003; Naber, 2008).

The aims of this systematic review were: 1) to identify all currently available SRQs used in the assessment of mental health patients' subjective experiences of side effects, 2) evaluate the characteristics of the SRQs and 3) to assess the psychometric properties of each of the SRQs.

## 2. Methods

### 2.1. Search strategy and study eligibility

The main objective of the search was to identify all currently available SRQs that assess the subjective experience of side effects and distress levels caused by psychotropic medications in mental health patients.

Electronic databases Medline, PsycInfo, EMBASE, Informat, Science Direct, PubMed, Web of Science and Google Scholar were searched without any language restrictions according to the Prisma criteria (Liberati et al., 2009). This systematic review included literature published until 31 January 2013. The combination of search terms used with each database was:

- 1) antipsychotic or antidepressant or mood stabilizer or anti-anxiety or psychotropic or neuroleptic medication AND,
- 2) side effect or adverse effect AND,
- 3) questionnaire or instrument or tool or assessment or checklist AND,
- 4) self-report or self-rated AND,
- 5) perception or subjective experience or belief or attitude.

The search results from the databases were collated and duplicate results were eliminated. Reference lists of identified papers were searched to locate additional papers. These were further screened for eligibility based on the following inclusion criteria:

- 1) Published in English.
- 2) Published in peer-reviewed journals.
- 3) Evaluate SRQs that assess more than one specific type of side effect.
- 4) Report on the development and validation of psychotropic medication side effect SRQs.

The results were screened for suitability independently by three investigators analyzing full-text articles after checking titles and or abstracts. Disagreements were resolved by consensus.

### 2.2. Data extraction and analysis

The shortlisted studies were then analyzed and where available the following data were extracted:

- 1) Study design and methodology.
- 2) Inclusion criteria.
- 3) Exclusion criteria.
- 4) Participants (sample size and demographics).
- 5) Time frame between baseline and follow-up.
- 6) Psychometric validation reported.
- 7) Characteristics of the SRQ.
- 8) Limitations.
- 9) Use in clinical practice.
- 10) Health outcomes derived.

We adopted a narrative approach to describe the characteristics of the studies reporting on development and validation of SRQs.

### 2.3. Quality assessment

Following the identification of the SRQs (Aim 1), the studies identified for this systematic review were assessed for quality. To meet Aim 2, studies were evaluated using an amended version of Crombie's critical appraisal of survey designs (Crombie, 1996). The characteristics that were chosen from the criteria are as follows:

- 1) Were the aims clearly stated?
- 2) Was there discussion of how the items on the SRQ were generated?
- 3) Was a pilot study done on the use of the SRQ?
- 4) Were demographic details of subjects provided and how the sample was obtained?
- 5) Were the limitations stated?
- 6) Was there a discussion of generalization? This is a measure of the extent to which the results can be generalized to other times and other locations.
- 7) What implications did the study have for clinical practice? Are the findings likely to be true and if so, were the conditions in which the study was carried out likely to be similar to other clinical settings?

To meet Aim 3, measures were evaluated using an amended version of the review criteria developed by the Scientific Advisory Committee of the Medical Outcomes Trust (Lohr et al., 2002). The assessments chosen from the criteria include the main psychometric issues:

- 1) Was a clear description given of the concept and the population being assessed?
- 2) Was completion time of the SRQ provided?
- 3) Was content validity tested?
- 4) Was the questionnaire refined as a result of content validity testing?
- 5) Was criterion validity tested?
- 6) Was construct validity tested?
- 7) Was internal consistency tested?
- 8) Was test-retest reliability tested?
- 9) Was alternate form reliability tested?

Two reviewers conducted quality assessments of the studies independently. They compared their final results and any discrepancies were resolved by discussion and consensus.

## 3. Results

A total of 531 articles were initially identified by the search strategy. Following a review of titles and or abstracts, 96 articles were shortlisted for detailed analyses by three sets of reviewers based on the abstracts. A final total of six papers were identified as relevant to this study (Fig. 1).

### 3.1. Aims 1 and 2 (identified SRQs and study characteristics)

This review identified six SRQs currently available that can be used in the assessment of mental health patients' subjective experiences of medication side effects (Day et al., 1995; Dott et al., 2001; Lindstrom et al., 2001; Wolters et al., 2006; Waddell and Taylor, 2008; Mojtabai et al., 2012). An evaluation of the characteristics of each study is shown in Table 1. There was significant variation between studies in terms of design, duration, validation methods and outcomes. There were three longitudinal studies (Day et al., 1995; Wolters et al., 2006; Waddell and Taylor, 2008), one prevalence study (Lindstrom et al., 2001), a cross sectional (Mojtabai et al., 2012) and a pilot study (Dott et al., 2001). Sample sizes varied from 50 to 320 patients, and settings varied from patients' homes to clinics. All the studies reported the development of an SRQ and tested their respective SRQs on a population of patients with schizophrenia spectrum disorders.

The following summarizes each of the six identified questionnaires described in Table 1.

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