

A New Patient Reported Outcome Measure of Anti-Psychotic Medication Side Effects

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1. INTRODUCTION

- Anti-psychotic medications are associated with adverse effects which can impact on quality of life and are associated with poor adherence and relapse (Haddad et al., 2011).
- There is a need for regular side effects monitoring so clinicians and service users can make informed treatment decisions (Haddad and Dursun, 2008).
- Increasing the level of information used to evaluate the side effects of anti-psychotics from the point of view of the service user, who may have additional and different concerns to those regarded as relevant by clinicians, would be of value.

Aim

- To develop a patient-reported outcome measure of anti-psychotic medication side effects.

2. METHODS

An innovative participatory methodology was used to maximise the opportunity for service user involvement (Rose et al., 2011).

The Delphi Exercise (n=9)

- An initial bank of items was drawn from three existing side effects measures (LUNERS, Crawford et al., 2011, GASS, Waddell and Taylor, 2008, ANNSERS, Yusufi et al., 2005).
- A group of psychiatrists and pharmacists determined the relevance and importance of specific items for inclusion in the new measure.

The Focus Groups (n=15)

- Two focus groups of service users allowed for the identification of the most important side effects to service users.
- Service user researchers constructed a measure from these qualitative data and the Delphi exercise.

The Psychometric Evaluation and Feasibility Study

Participants (N=75)

- N=43 on anti-psychotic medication (for a minimum of 1 month, not on anti-depressant medication) with a diagnosis of a schizophrenia.
- N=32 on anti-depressant medication (for a minimum of 1 month, not on anti-psychotic medication) with a diagnosis of depression.

Measures

- The new anti-psychotic side effects questionnaire.
 - 54 side effect items – each with a question on intensity, distress and life impact.
- A feasibility questionnaire.
- General Health Questionnaire (GHQ-12, Goldberg, 1978).
- Short Form Health Survey Version 2 (SF-36v2, Ware Jr., 2000).
- Beck Depression Inventory (BDI, Beck, 1996 – completed by participants on anti-depressants).
- Brief Psychiatric Ratings Scale (BPRS, Lukoff et al., 1986 – completed by participants on anti-psychotics).

Participants completed measures twice, one week apart.

3. RESULTS

Demographics of participants

	Anti-depressants	Anti-psychotics
Women (%) / Men (%)	15 (47) / 17 (53)	16 (37) / 27 (63)
Mean Age (sd, range)	47.59 (12.7, 19-66)	45.8 (9.9, 24-64.5)
White (%) / BME* (%)	21 (66) / 11 (34)	13 (30) / 30 (70)

*Black Minority Ethnic

Feasibility

- 84% reported that the measure covered everything, 97% felt it was easy to understand and 95% found it easy to fill in.
- 3% disliked filling in the measure and 21% found some of the items upsetting (e.g. items associated with sexual problems).
- Some items were relabelled to improve understanding.

Reliability

- Overall, the measure showed strong test-retest reliability ($r=0.81-0.96$, $p\leq 0.01$), service users' answers were reliable over time.
- At item level, weighted Kappa coefficient indicated at least fair agreement for intensity items and non-significant coefficients emerged in the cases of "fits", "rash" and "catatonia" side effects .
- 9 out of 54 items were not stable for levels of distress. This may be due to their low prevalence and therefore reduced power to detect effects.

Validity

- Participants with high levels of psychosis symptoms did not endorse more side effects than those with low levels of psychosis symptoms (mean 22.7 versus 19.3 respectively; $Z=0.863$, $p=0.388$).
- Those with high levels of psychosis symptoms reported significantly higher life impact (median 9 versus 0; $Z=-2.858$, $p=0.004$) which is expected given that the symptoms plus the side effects are likely to have a higher impact on everyday life.
- The pattern of side effects reported was different between the anti-depressant and anti-psychotic medication groups.

4. CONCLUSIONS

- A participatory methodology was used to generate a self-report questionnaire measuring service users' experience of anti-psychotic medication side effects.

Implications

- The measure is easy to understand and complete and is therefore suitable for use by service users.
- It is a reliable and valid measure of anti-psychotic medication side effects in service users with schizophrenia.

Further Research

- The side effects measure will be completed by 300 service users, in order for a factor analysis to be carried out.

5. KEY REFERENCES

- Haddad, P.M., & Dursun S.M. (2008). Neurological complications of psychiatric drugs: clinical features and management. *Human Psychopharmacology*, 23, 15-26.
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- Rose, D., Evans, J., Sweeney, A., & Wykes, T. (2011). A model for developing outcome measures from the perspectives of mental health service users. *International Review of Psychiatry*, 23, 51-46.