Reviewer’s report

Title: Experiences from consumer reports on psychiatric adverse drug reactions with antidepressant medication: a qualitative study of reports to a consumer association

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Reviewer: Ronald Meyboom

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This is for several reasons an important manuscript.

1. The rapid and extremely wide use of the SSRIs after their introduction and the remarkably slow increase, on the other hand, in the knowledge and understanding regarding their effectiveness and benefits as well as their safety and side effects profiles, are likely to continue to be a matter of serious interest and concern.

2. It has taken decades before finally also reports from patients (and in many countries the same is true for reports from pharmacists) became ‘accepted’ at pharmacovigilance centres. As this study shows, though, ‘accepting’ is not enough. A patient-observation is not the same as a professional observation. The common practice of trying to lift patient reports to a ‘higher’ level and to give them a more ‘scientific’ appearance, for example by translating the event by adding one or more MedDRA terms, may not be the right way to go. This may paradoxically distort the picture, hide its message or delay a signal. The challenge to using patient-reports is to do what physicians do: first to ‘listen’ to what the patient has to say and to show. This study illustrates the extra value of patient-reporting.

3. Although it may be criticised as non-scientific by for example a company or a regulator, I think that the way the authors choose to go (‘content analysis’) has been good: their findings sharpen our view of what may happen to patients while using an antidepressant, of the complex interaction between drug, patient and doctor. It enables to formulate a sensible interpretation of the data in the reports, from which in a natural way further research questions follow, which may in turn be tested in the best possible and rational way. A danger with real-life information such as in this study is that the data that have produced the evidence (preliminary as it may be) are subsequently tried or even forced to subsequently also provide the proof. This is not the way that science goes, however.

4. First of all, this study increases our knowledge of the clinical signs and symptoms that SSRI side-effects may induce and the conditions under which they may occur (for example in a withdrawal attempt). Next the free text information in the reports is suggestive of a rather common failure in communication between prescribers and patients, of the situation that
experiences of patients differs from what the doctor expects, and next that the
doctor tries to adjust his patient to what is supposed to happen.

5. Inappropriate communication between physicians and patients, however, may
in turn lead to loss of confidence and trust and to suboptimal patient care.

For the above reasons, I recommend the acceptance of this paper. It may need
some modifications however and I could give further comments or suggestions.
At this moment I add a few points:

• The enthusiastic words in the introduction about the virtues of patient-reporting
raise, I believe, unrealistically high expectations. Pharmacovigilance and
'spontaneous reporting' have major limitations. This study nicely illustrates that
patient reports do have something to add to the professional reporting system,
but it is likely to be only a modest step forward. I recommend to give a more
realistic and sensible description of the hoped advantages of direct patient
involvement in pharmacovigilance.

• It is my experience that valuable ‘patient reports’ may be written or be submitted
by a family member or care taker, in particular with regard to psychotoxic drugs.
In this study 5 reports have been excluded "because being reported by someone
else". Obviously this is only a very small number, but in principle I would prefer
that such reports are also taken into account and be – somewhat separately –
studied and considered for inclusion. For example, often a mother or a wife may
give better or complementary information than an ill or confused patient.

• A strong point of these reports seems to be that they are fairly rich in detail. My
feeling is that there may possibly be even more to be learned from the reports, in
clinical-psychological (combinations of events or course of events, syndromes)
and perhaps also in pharmacological respect (receptor affinity versus sign or
symptom). If so, this could be done in further ('case series') study