Reviewer’s report

Title: Design and methods of the ‘Monitoring Outcomes of Psychiatric Pharmacotherapy’ (MOPHAR) monitoring program – a study protocol

Version: 0 Date: 19 Sep 2018

Reviewer: Fernanda Raphael Escobar Gimenes

Reviewer's report:

The paper explores an important subject to the clinical practice and to the quality of care provided for psychiatric outpatients. However, the introduction, background, objectives, methods and conclusion require quite a work as it currently doesn’t present a clear structure and a logical flow. I offer the following advice and critique to enhance its overall clarity, quality and value to the readership and beyond.

Title: Please, indicate that this paper refers to a study protocol

Background
Page 4, line 19: Please, consider the use of "adverse drug event" instead of "iatrogenic adverse effects".
Page 5, line 47: Please, capitalize "p" for "Monitoring Outcomes of psychiatric Pharmacotherapy"

Methods/Design
Perhaps the objectives of your project could be described in a separate section named "Objectives of the study".

Target population and setting
Although you affirm that the MOPHAR monitoring program can be implemented at any mental health care outpatient clinic, it is unclear whether you will implement the program in other mental health institutions beyond the one where the program is already being implemented or if the proposed study will be conducted only at this large secondary community mental health care outpatient department. Please, clarify this issue.
Please, add the exclusion criteria(s) for this study and specify the sample size.

The MOPHAR treatment team
Page 7, lines 21-33: You described how nurses conduct the medication reconciliation. I wonder if nurses have access to the medical prescription to enter the medications in the electronic prescribing system or if the nurses enter the information provided by the patients (verbally). If nurses have access to the medical prescription, I wonder if it is handwritten or electronic? I am concerned about the medication transcribing process because the literature shows that errors can occur during this process, especially if prescriptions are illegible. Would you, please, clarify the aspects of this process?
Lines 28-33: According to this sentence "The team must identify a clear workflow regarding the communication of results with other relevant health care professionals", but I wonder if the setting
where this program is already implemented has your own workflow of communication and how it happens. This is an important aspect of the program once gaps in communication during patient handovers is one of the major factors related to adverse events in healthcare settings.

In addition, I wonder if only healthcare settings with electronic medical record can implement the MOPHAR program or if the program can be implemented in every healthcare settings regardless of whether they have electronic medical records or not.

Online patient-filled questionnaires
You affirm that "after an invitation letter for the first appointment has being sent, patients are asked to fill in online questionnaires". I wonder if all patients have access to a computer and if not, how these questionnaires are filled? This information might interest the international audience, especially those countries with limited resources whose patients have no access to a computer.

Screening appointment with MOPHAR nurse
You informed that "… patients from most teams are asked in the invitation for the appointment to go to the laboratory for blood withdrawal in the week before the screening." Many readers will not be familiar with the health care system in Netherlands. Perhaps it might be interesting to describe how the process of laboratory test occurs in this country as it might be different from other countries. For instance, in some countries, patients require a physician order for laboratory test samples.

Page 13, lines 26-40: you described that "… the MOPHAR monitoring program also provides the opportunity for a long-term (longitudinal) prospective observational cohort study. The large amount of information collected in this patient-registry of MOPHAR can be used for research…", but what questions do you wish to address in this paper?

Page 14, lines 1-3: you affirmed that the (cost)effectiveness of the MOPHAR program will be accessed. However, this aspect was not presented anywhere else. Why is this important? A brief overview should be provided in the background section.

Please, provide details on the definitions used in this study. For example, what do you call an adverse event? (page 14, line 7)
Along the whole text, you use different words for expressing the same term (i.e. adverse effects, adverse events, adverse outcomes, etc). Please, consider the use of a theoretical framework (for example, the International Classification for Patient Safety, from WHO) and provide the definitions that will be adopted in this study.

It is not clear how you will access patient harm (adverse event) associated with the use of psychotropic drugs.

Informed consent
You affirmed that "all participants provided written informed consent", but I wonder about the new patients that will be included in this study. How will you address this ethical matter? What about the extra blood sample for future studies? Were the patients aware of this at the time they signed their consent form to participate in the MOPHAR program?

The sequence of the topics covered in this paper is peculiar. Please consider revision so it can gain in clarity. For instance, you may present the topics following the sequence:

1. Introduction and background,
2. Aims/Objectives,
3. Methods: study design / participants and setting(s) / the intervention (MOPHAR program) / outcomes assessments / data collection / planned data analysis / ethical approval, and
4. Conclusion.
In addition, if you pretend to develop more than one study, perhaps you could describe each study separately.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

No

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

No

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Unable to assess

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

**Quality of written English**
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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