Author’s response to reviews

Title: "Decision-making capacity for research participation among addicted people: a crosssectional study"

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Author’s response to reviews:

We would like to first thank the editor for his efforts and for identifying both the strong and weak points of our manuscript. We trust that our responses to the editors’ suggestions will render the manuscript suitable for publication in BMC medical ethics.

Editor Comments to Author:

1. On assessing your revised manuscript, we have noticed that sections of your text overlap with a previously published article, 'Assessment of Capacity to Consent to Research Among Psychiatric Outpatients: Prevalence and Associated Factors' by Morán-Sánchez et al. Unfortunately this is unacceptable for publication and we will require you to reword some sections of your manuscript where text has been lifted from this previous publication. Please refer to the attached document, with particular attention to the discussion, limitations and conclusions sections highlighted in **RED**(numbered 1). It is not necessary for you to revise other highlighted sections.

The previous article you mentioned is one published by our group and some conclusions and the way is written is similar. We will reword the highlighted sections you mentioned in the last version of the manuscript which was approved by the reviewers.

Discussion

We believe this study to be important because To our knowledge this is the first one study to that specifically assess the capacity to provide consent to research evaluate levels
of capacity to consent to research among people with SUD using a standardized instrument such as the MacCAT-CR.

Patients with SUD showed the worst performance on the measures of the MacCAT-CR, particularly especially in terms of the Understanding and Appreciation disclosed dimensions. Given the contextual nature of decisional capacity, as well as the nature characteristics of the MacCAT-CR interview, a comparison of results across studies is somewhat difficult; the MacCAT-CR The scale does not provide ‘cut-off scores’ has no established cut-score nor is there an algorithm for categorical determinations of capacity or incapacity. Thus Therefore; there is not a no particular level of ability is which represents of determinative adequate capacity in all circumstances [35]. Mean levels of MacCAT-CR performance scores vary widely within diagnostic groups different disorders. We found that the mean Understanding total score in our SUD group was 20.1 points; and 5.0 points on the Reasoning dimension. We have no We didn’t find previous research studies about SUD and MacCAT-CR performance to compare with. These results Our findings will have to be explored in future studies further research.

In the present study we found an association between education level is associated with and mental capacity. This may be due to some several factors such as cognitive impairment decline.

Only one of the considered variables remained independently associated with lack of capacity incapacity on multivariate analysis: the cognitive state.

In our study when the other variables associated with lack of capacity incapacity on the multivariate analysis are considered, gender has no longer a significant impact on the probability of being capable.

Symptom severity, as measured by GAF and CGI scores was associated with incapacity lack of capacity in this research study. Our findings research suggest that the dual diagnosis severity, as measured by lower social functioning may be a factor in the decisional process.

It is widely held that patients subjects are deemed competent, unless it can be proved otherwise, to participate in the decision-making informed consent process. If the patients participants do not fully comprehend the nature of the procedures to which they are consenting

Limitations

There are a number of limitations that should be considered when interpreting the results. First, our findings are based on data collected from a limited number of subjects in a specific research context in an urban located centre, which may limit the generalizability
of the findings study was carried out in an urban setting and it was restricted to a limited number of outpatients which may limit the generalizability generalisation of the results. Further research is necessary to assess our results in other settings and participant groups. Studies with larger sample sizes would also allow investigators to conduct multiple-regression analyses with a greater number of independent variables in order to confirm all the univariate associations in the logistic regression model.

A second limitation is that the data used for this analysis is cross-sectional and so do not allow us to examine changes in consent-related abilities over time, and to identify predictors of change, so that the need for additional protections of this sort might be better assessed.

A second limitation arises from the cross-sectional data origin. The results presented here do not allow us to examine changes in consent-related abilities over time, and nor to identify predictors of change. Consequently, prospective studies about SUD and capacity to consent to research should be conducted to identify those people that may require safeguards tailored to protect their rights so that the need for additional protections of this sort might be better assessed.

Another limitation that should be considered when interpreting the results is that both the non-random nature of the sample and the absence of other SUD (such as heroine and anxiolytics/hypnotics use disorders) raise questions about the generalizability of the results. Future studies should assess capacity in these SUD.

Conclusions

Our study demonstrates that a significant proportion of people with SUD had mental capacity to make decisions on research.

The findings of our study provide evidence that a large proportion of individuals with SUD had decisional capacity for consent to research. It is therefore inapropriate to draw conclusions about No absolute statement judgement about decisional capacity to make research decisions can be driven merely on the basis of a SUD diagnosis due to the diagnosis, because most of addicted people with SUD remain capable of giving autonomous consent under most circumstances. In the absence of acute withdrawal or intoxication or advanced cognitive impairment, we should assume that addicted persons possess decision-making capacity. Thus, the assumption that a person suffering from a SUD will have always impaired decision making abilities is unfounded and stigmatising the view that people with SUD would ipso facto lose decision-making power for research consent is flawed and stigmatising. Institutional Review Boards and investigators should consider this caveats as they decide which populations or individual subjects may require more intensive screening evaluation or education further educational efforts to enhance
decisional capacity, especially for greater-than-minimal-risk studies like our hypothetical study was.

2. Please remove the funding, consent and ethics sections from the end of the manuscript, leaving the ethics and consent statements in the methods sections and the funding information in the acknowledgements.

We have removed and replaced the sections the editor suggests:

Competing interests

The authors declare that no competing interests exist.

Authors´contributions

IMS and MDPC conceived and designed the study. IMS drafted the manuscript. MSM and BAA conducted the study. IMS, ALM and MDPC reviewed and scored the interviews. ALM and MDPC made substantial inputs to the analysis and interpretation of data and revision of the article. All authors approved the final version of the manuscript.

Acknowledgments

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Funding There wasn’t any funding source.

Informed consent Informed consent was obtained from all individual participant included in the study.

Ethics approval The ethics committee of the referral hospital approved the study.

3. Please provide abbreviations section at the end of your manuscript. Specifically please define the abbreviation IC and for clarity do not use this abbreviation in the statements regarding consent for this study.

We provide the abbreviations section at the end of the manuscript as the editor suggests. We will no longer use the abbreviation IC in the manuscript.

Abbreviations

CGI: Clinical Global Impression Scale; CI: confidence interval; DSM-5: Diagnostic and Statistical Manual of Mental Disorders; GAF: Global Assessment Functional Scale; MacCAT–CR: MacArthur Competence Assessment Tool for Clinical Research; MMSE: Mini-Mental State Examination; NPCs: non psychiatric comparison subjects; OR: odds
ratio; SD: standard deviation; SUD: substance use disorders; THC: Tetra hidro cannabinol; UN: United Nations; VIF: variance inflation factor.