Author’s response to reviews

Title: PREVALENCE AND CORRELATES OF NON-ADHERENCE TO IMMUNOSUPPRESSANTS AND TO HEALTH BEHAVIOURS IN PATIENTS AFTER KIDNEY TRANSPLANTATION IN BRAZIL - THE ADHERE BRAZIL MULTICENTRE STUDY: A CROSSSECTIONAL STUDY PROTOCOL

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Version: 1 Date: 17 Apr 2017

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Juiz de Fora, April 17th 2017

Hayley Henderson
Editor,
BMC Nephrology

Dear Dr. Henderson,

I am submitting our paper titled ‘Prevalence and correlates of non-adherence to immunosuppressants and to health behaviours in patients after kidney transplantation in Brazil – The Adhere Brazil Multicentre Study: A cross-sectional study protocol’ to BMC Nephrology as a study protocol. The paper was co-authored by Fernando Antonio Basile Colugnati, Elisa Oliveira Marsicano, Sabina De Geest, and José Osmar Pestana Medina, on behalf of Adhere Brazil Consortium Group.
In this paper, we describe the rationale, design and methodology of the ADHERE BRAZIL study which aims to assess the prevalence and variability of non-adherence to immunosuppressants and to health behaviours among adult kidney transplant recipients in Brazil, and to assess the multilevel correlates of non-adherence. Brazil is in a unique position to study these multilevel correlates and risk factors, because it has the largest public transplantation program in the world with regional differences with regard to access to health services and service implementation. This is an important study as non-adherence to immunosuppressive therapy is a prevalent risk factor for poor clinical and economic outcomes after kidney transplantation (KT), and has contributed to the inability to improve the long-term graft survival over the past decade. Understanding the multilevel correlates and risk factors of non-adherence would guide the development of innovative interventions, as well as identify the optimal level for implementation, namely at the patient, health care provider, KT centres, and/or health care system level.

The trial is registered at ClinicalTrials.gov on 10/10/2013, NCT02066935. The methods were approved by our twenty institutional ethics review boards (ERB) and informed consents are being obtained from participants. Please find in an additional file, the full names and affiliations of the coordinator and all participating centres, and full names and affiliations of all ERBs. ERBs are coordinated nationally and use a national web based system to manage all submissions. Once a project is approved, a reference number is generated. We have provided these approval numbers as well. Other relevant aspect of Brazilian Ethics in Research System is about the ethical approvals. These reports are written by the coordinator of the ERB, after accessing the web based system (named Plataforma Brasil) which is controlled by unique identification and password. Because of this, none of these reports is physically signed. Original and translated copies of ethical approval reports of all 20 centres and funding approvals were sent by e-mail to BMCSeriesEditorial@biomedcentral.com on April 17th 2017.

As requested, the "Consent to publish" section was included as part of the Declarations section, the "Authors' Contribution" section was revised, and a language editing was done.

The study is ongoing, the data collection began in December 2015. We also ensure that the study has strictly followed the STROBE guidelines and a STROBE checklist for observational studies is included as an additional file.
In submitting our manuscript for peer review, I acknowledge that its content has not previously been published or presented elsewhere, in part or in entirely, and is not under consideration by another journal. All authors have reviewed and approved the version submitted for peer review to BMC Nephrology. All authors accept ethical responsibility for the release of the content of this original study. The authors have no conflicts of interest to declare.

Thank you for your consideration. I look forward to hearing from you.

Sincerely,

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