Author's response to reviews

Title: The use of risk sharing tools for post adoption surveillance of a non-pharmacological technology in routine practice: results from a one year experience

Authors:

Carlos Campillo-Artero (carlos.campillo@ibsalut.es)
Francisco M Kovacs (fmkovacs@kovacs.org)

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Author's response to reviews: see over
The use of risk sharing tools for post adoption surveillance of a non pharmacological technology in routine practice: results from a one year experience

Version: 6 Date: 6 November 2012
Reviewer: Iben Axén

Reviewer’s report:

I am satisfied with your comprehensive answers to my concerns.

The authors thank the reviewer for this comment.

Major compulsory Revisions: I have only one more: did you obtain an ethical permission to perform the study?

According to the Spanish law, studies using data gathered in routine clinical practice do not need to request ethical permission from an Institutional Review Board, when: a) patients have given written informed consent for their data to be used for this purpose by the institution(s) providing the care, and b) data are not transferred from these institutions to third parties.

In this case, the evaluation and assessment procedures were defined in the clauses of the contract.

Following the reviewer’s comment, the manuscript has been modified, and the updated version reads as follows:

• First paragraph under “Intervention”

Following the application conditions in which NRT had proven effective, safe, and cost-effective,\textsuperscript{40, 51, 57} specialists at the NRT units assessed indication criteria. Patients complying with indication criteria were presented written informed consents for undergoing NRT and for allowing the use of their data for this study. Units in which the interventions were performed, and physicians who performed them, had been certified following specialised professional standards.\textsuperscript{58} According to the Spanish law, this study did not need to be submitted to an Institutional Review Board.

• First paragraph under “Results”

During 2011, 909 patients referred by the Ib-Salut for NP (244 patients), TP (61) and LBP (604), underwent NRT and were discharged before the 31\textsuperscript{st} of December 2011. All patients complying with indication criteria for NRT, signed their informed consents.

Sincerely,

Carlos Campillo-Artero, MD, MPH, PhD
Francisco M. Kovacs, MD, PhD