Author’s response to reviews

Title: The Impact of Regional Co-payment and National Reimbursement Criteria on Statins use in Italy. An Interrupted Time-Series Analysis.

Authors:

Gianfranco Damiani (gdamiani@rm.unicatt.it)
Bruno Federico (b.federico@unicas.it)
Angela Anselmi (angela_anselmi@libero.it)
Caterina BNA Bianchi (caterinabianchi@hotmail.it)
Giulia Silvestrini (silvestrinigiulia@gmail.com)
Lanfranco Iodice (lanfranco.iodice@gmail.com)
Pierluigi Navarra (pnavarra@rm.unicatt.it)
Roberto Da Cas (roberto.dacas@iss.it)
Roberto Raschetti (roberto.raschetti@iss.it)
Walter Ricciardi (wricciardi@rm.unicatt.it)

Version: 2 Date: 20 December 2013

Author’s response to reviews: see over
Point-to-point answers to reviewer’s comments:

Reviewer 1: Gianluigi Savarese

We would like to thank the reviewer for his useful comment. Following the suggestion of a second reviewer, we have slightly modified the manuscript, along with tables and figures. We hope that this corrections made the manuscript even more worth of being published.

Reviewer 2: Gabriel Sanfélix-Gimeno

We would like to thank the reviewer for his comments that helped to greatly improve our manuscript. We tried to correct the manuscript as suggested in every single point. We hope that the manuscript is now suitable for publication.

Major Compulsory Revisions

- Throughout the manuscript, statements regarding the effect of the policies measured are too suggestive of a causal link between observed prescribing rates and the policies (e.g. “The revision of the AIFA Note in November 2004 caused a remarkable reduction in the upward trend of statin use”). It should more clearly express that a temporal association was observed, that may or may not have been causal.

Answer:
Thanks for this useful comment. The text was entirely screened and corrected as requested, wherever it was needed.

- In the abstract, the “conclusions” paragraph should be limited to the conclusions drawn by the study results. The study was not designed to compare different drug reimbursement policies; therefore, the statement “The restriction to reimbursement Interventions had a greater impact on consumption than the regional co-payment” should be avoided. The conclusion should be based on their results: the national revision of the reimbursement criteria was associated with an immediate drop and a decrease in trend of statin use, while the regional copayment was associated with a small increase in trend of statin use.

This commentary also applies to the manuscript conclusions.

Answer:
Thanks for highlighting this point: we modified both the abstract and the conclusion paragraph to better describe study’s main findings.
- In the last paragraph of the introduction section, the aim seems to be redundant. It should read: The aim of this study was to evaluate the impact of the national and regional cost containment measures on statin use in Italy during the period May 2001 – December 2007.

Answer:
The sentence has been corrected as requested.

- In the results section the authors make interpretations of some of the results (i.e. “the effect of the copayment was overall negligible”). Authors’ interpretations of the results should be avoided in this section, which should be restricted to the presentation of the findings.

Answer:
We deleted that interpretation from the results section. Thanks for your comment.

- Further limitations should be addressed. One of the most important limitations of the study resides on its observational nature. Observational studies do not allow establishing a cause-effect relationship; many other events happening simultaneously may have influenced prescribing patterns during the span of the study.

Answer:
We added another limitation in the discussion section to highlight this aspect. Thank you for this useful comment.

- The methodology used to address the main objective is appropriate, however, it should not be pointed as a strength of the study. It is expected that appropriate methods to address the research questions are used.

Answer:
The point was removed from the discussion on study’s strengths.

- In the Methods section, Statistical analysis subsection, the descriptive analysis should be further detailed (descriptive analysis by regions with and without copayment, descriptive statin use trends plot, etc.)

Answer:
A more detailed explanation of the descriptive analysis performed was added at the beginning of the statistical analysis subsection. Thank you for the suggestion.

- In Figures 1 and 2, the title of the y-axis should be written in English (that is, DDD/1000 inh. day). Also the heading of both figures should be more appropriately written. It should state: Monthly statins consumption (DDD/1000 inh. day) in the two groups of regions.
Answer:
*We modified the title of the y-axis of both figures along with the heading as suggested. Thank you.*

-In Figure 1, a footnote explaining the meaning of the arrows should be added.

Answer:
*The footnote was added. Many thanks.*

-Although the language is generally acceptable, it needs some language corrections before being published.

Answer:
*The manuscript have been now revised by a mother tongue. Thank you.*

Discretionary Revisions

-In the third paragraph of the results section the authors describe the selection of the model. Maybe this part would fit better in statistical analysis subsection of the methods section.

Answer:
*This part have been moved to the suggested subsection. Thank you for this comment.*

-In Table 2, authors included all the parameter estimates from the segmented regression analysis. However, the estimates for the dummy variables included are not very informative and make the table larger and harder to read. These estimates may not be necessary.

Answer:
*The parameter estimates for the regions were deleted. Thanks for your suggestion.*