Author's response to reviews

**Title:** Validation of Diabetes Mellitus and Hypertension diagnosis in computerized medical records in Primary Health Care.

**Authors:**
Carmen de Burgos-Lunar (carmenblunar@hotmail.com)
Miguel A Salinero-Fort (Miguel.salinero@salud.madrid.org)
Juan Cárdenas-Valladolid (icardenas.gapm04@salud.madrid.org)
Sonia Soto-Díaz (sosoto.gapm04@salud.madrid.org)
Carmen Y Fuentes-Rodríguez (carmeny.fuentes@salud.madrid.org)
Juan C Abánades-Herranz (jabanades.gapm04@salud.madrid.org)
Isabel del Cura-González (icura.gapm09@salud.madrid.org)

**Version:** 3 **Date:** 19 August 2011

**Author's response to reviews:** see over
Dear Editor,

Thank you kindly for inviting us to resubmit our manuscript entitled: “Validation of Diabetes Mellitus and Hypertension diagnosis in computerized medical records in Primary Health Care”.

We thank the reviewers for their constructive critique and the many helpful suggestions and corrections which have improved the manuscript.

In the following paragraphs we provide the point-by-point reply to the reviewer comments. We expect that the flagged points raised by the reviewer have been sufficiently explained and corrected. We remain at your disposition for any additional information you may require.

The most significant changes are:

− The inclusion and exclusion criteria have been explicitly provided.
− The wording was clarified and the text has been checked by a native English speaker.

With kind regards, on behalf of all authors,

Carmen de Burgos Lunar,

Hospital Carlos III
Calle Sinesio Delgado 10
28029 Madrid, Spain
Reviewer's report
Title: Validation of Diabetes Mellitus and Hypertension diagnosis in computerized medical records in Primary Health Care.
Version: 2 Date: 24 June 2011
Reviewer: Jennifer H Garvin

Comment [jhg1]: Not sure what you mean here- do mean that this is the most prominently used or the recommended guideline in a given country- need more information

Comment [jhg2]: Do you mean the reference standard or gold standard against which you measure the sensitivity, specificity, and determine PPV?

Considering this comments, we have clarified the text:

Old paragraph:

“The aim of this study is to validate the diagnosis of hypertension and diabetes mellitus in the computerized clinical records of primary health care, taking the diagnosis criteria established in the main clinical guidelines as standard reference.”

New paragraph:

“The aim of this study is to validate the diagnosis of hypertension and diabetes mellitus in the computerized clinical records of primary health care, taking the diagnosis criteria established in the most prominently used clinical guidelines as the gold standard against which what measure the sensitivity, specificity, and determine PPV.

The gold standard for DM was the diagnostic criteria established in 2003 American Diabetes Association Consensus Statement for diabetic subjects. The gold standard for HTN was the diagnostic criteria established in the Joint National Committee published in 2003.”

Comment [jhg3]: I think a word is missing- global...

We have replaced “general” by “overall”. Now the sentence is: “Results were shown overall and stratified by sex and age groups.”

Comment [jhg4], Comment [jhg5]: With the reference standard as determined by the guideline?

Yes, it is, we have included the text “with the reference standard as determined by the guideline” in the sentences for a better comprehension:

“The agreement for diabetes mellitus with the reference standard as determined by the guideline was almost perfect (κ =0.990), with a sensitivity of 99.53%, a specificity of 99.49%, a positive predictive value of 91.23% and a negative predictive value of 99.98%. Hypertension diagnosis showed substantial agreement with the reference standard as determined by the guideline (κ = 0.778), the sensitivity was 85.22%, the specificity
96.95%, the positive predictive value 85.24%, and the negative predictive value was 96.95%.

**Comment [jhg6]:** This sentence does not make sense. Do you mean, our results substantiate the validity of using diagnoses of diabetes and hypertension found within the computerized clinical records for epidemiologic studies?

Considering this comment, we have replaced the paragraph "Our results enable to use the diagnoses of diabetes and hypertension of the computerized clinical records as a valid tool to perform epidemiological studies." by the new paragraph "Our results substantiate the validity of using diagnoses of diabetes and hypertension found within the computerized clinical records for epidemiologic studies."

**Comments [jhg7] and [jhg8]:**

[jhg7] Tense agreement should be the same as *
[jhg8] *- the tense needs to agree- both should be in past tense- this is also a reference from 2007.

We have change the verb tense, now they were both in past tense.

**Comment [jhg9]:** Need a reference

We provide the bibliographical reference:
Bibliographical reference 5: General Practice Research Database [Internet]. Available at http://www.gprd.com

**Comment [jhg10]:** Perhaps it is more accurate to say that there are several approaches found in the literature but that there is not an agreed upon standard approach to evaluate the quality and accuracy.

Considering this suggestion, we have replaced the paragraph "There is no standardized methodology to evaluate the quality and accuracy of the information contained in the clinical-administrative databases." by the new paragraph "There are several approaches found in the literature but there is not an agreed upon standard approach to evaluate the quality and accuracy."

**Comment [jhg11]:** Hypertension is usually abbreviated using HTN rather than HT in the US.

We have replaced "HT" by "HTN" in all the manuscript

**Comment [jhg12]:** Please specific the guideline and how it is used in the country.

Considering this suggestion, we have replaced the paragraph "..., taking the diagnosis criteria established in the main clinical guidelines as standard reference." by the new paragraph "..., taking the diagnosis criteria established in the most prominently used clinical guidelines as the gold standard."

The clinical guidelines which were used are detailed in the section "methods".
Comment [jhg13]: I think you mean have a computerized patient record- if this is correct please state that.

Yes, that is what we tried to mean. We have changed the text for a better comprehension:
Old paragraph: "All centers are computerized and have been working for at least 10 years with CCR."
New paragraph: "All health centers have computerized patient records since at least for 10 years."

Comment [jhg14]: I am not sure what the it refers to.

Considering this comment, we have clarified the text, and have replaced “It is a search system based on clinical labels that assign automatically the code.” by “This instrument is a search system based on clinical labels that assign automatically the code.”

Comments [jhg15],[jhg16] and [jhg17]: Please provide the inclusion and exclusion criteria explicitly.

Considering this comments, we have replaced the paragraph

“The study population comprised all patients older than 18 years with CCR in the health centers of health area 4, the first of January 2010. The units of analysis were the CCR of patients older than 18 with an ICPC codes corresponding to DM (32,377 patients with code T90) and to HT (91,065 patients with codes K86 or K87), respectively. Furthermore, some patients also had to be excluded from our analysis because even though they met the inclusion criteria, they had not at least one plasma glucose measurement (7.3%) or two BP measurements (22.9%) in their CCR for the validation of DM and HT respectively. “

By the new paragraph

“Inclusion and exclusion criteria

The study population comprised those patients who met the following inclusion criteria: had at least one record within the CCR in the health centers of health area 4 as of January 1st 2010; over 18 years of age; had an ICPC code in their CCR corresponding to DM (32,377 patients with code T90) or to HTN (91,065 patients with codes K86 or K87), respectively.

Patients were not included if they met any of the following exclusion criteria: had not at least one plasma glucose measurement (7.3%) or two BP measurements (22.9%) in their CCR for the validation of DM and HTN, respectively."

Comment [jhg18]: I am not sure what q is. Please specify

Probability of the desired outcome = \( p \)
Probability of not getting the desired outcome = \( q = 1 - p \)
We have replaced "q" by "(1-p)" in the manuscript for a clearer understanding.
Comment [jhg19]: Do you mean to adjust for foreseeable loss...?

Yes, that is what we tried to mean. We have changed the paragraph for a better comprehension:

Old paragraph: "We increased it up to 423 because a 10% foreseeable loss between the sampling and the validation of the diagnosis (change of address, death or other reasons)."

New paragraph: "We increased it up to 423 to adjust for a foreseeable loss of 10% between the sampling and validation of the diagnosis (change of address, death or other reasons)."

Comment [jhg20]: Please specify the “main” is as soon as possible in the manuscript.

The clinical guidelines which were used are detailed in the section "methods".

Comment [jhg21]: In the US we use the designation of family practice, general internal medicine, primary care, general internal medicine

We have replaced "family doctors" by "general practitioners", which is a MeSH term

Comment [jhg22]: Is this edited version correct?

Yes, it is:

“We conducted a peer evaluation with two reviewers with a third evaluator who resolved discrepancies”

Comments [jhg23], [jhg24], [jhg26] and [jhg27]: Do you mean overall?

Yes, that is what we tried to mean. We have replaced "general" by "overall".

Comment [jhg25]: Please specify agreement of what with what

Considering this comment, we have clarified the text. Now the sentence is “The results of the study show a very high agreement of the diagnosis of DM in the CCR with the gold standard, and also a high sensitivity and specificity of the diagnosis of DM.”

Comment [jhg28]: Do you mean- these findings can be used to alert clinicians of subgroups for which the interventions could be more beneficial?

Yes, that is what we tried to mean. We have changed the paragraph for a better comprehension:

Old paragraph: “This could permit reorient clinical practice, prioritizing the interventions in the subgroups that would be more beneficiated.”

New paragraph: “These findings can be used to alert clinicians of subgroups for which the interventions could be more beneficial.”
Comment [jhg29]: This is quite short- I would suggest that you decrease the discussion and increase the conclusion section.

We have increased the content of the conclusions by adding a new paragraph: “However, the HTN diagnosis in the CCR has lower sensitivity than DM diagnosis, especially in diabetic patients. Therefore, in this group of patients, the code of HTN diagnosis in the CCR is not enough in order to detect people without HTN since there would be selected a high amount of false negative results.”

Once again, we would like to thank the reviewer for their positive comments and suggestions for improvement. We hope that we have clarified all the concerns, and that the manuscript is now acceptable for publication at BMC Medical Research Methodology.