Author's response to reviews

Title: Dynamics of cinacalcet use and biochemical control in hemodialysis patients: A Retrospective New-User Cohort Design

Authors:

Diane Reams (diane.reams@unc.edu)
Paul J Dluzniewski (pdluznie@amgen.com)
Thy P Do (thypdo@gmail.com)
Susan V Yue (syue@amgen.com)
Brian D Bradbury (bradbury@amgen.com)
Abhijit V Kshirsagar (abhijit_kshirsagar@med.unc.edu)
Alan Brookhart (abrookhart@unc.edu)

Version: 2
Date: 10 August 2015

Author's response to reviews: see over
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Authors:
B. Diane Reams, PharmD, MPH
Email: diane.reams@unc.edu

Paul J. Dluzniewski, PhD
Email: pdluznie@amgen.com

Thy P. Do, PhD
Email: thypdo@gmail.com

Susan V. Yue, MD
Email: syue@amgen.com

Brian D. Bradbury, MA, DSC
Email: bradbury@amgen.com

Abhijit V. Kshirsagar, MD, MPH
Email: abhijit_kshirsagar@med.unc.edu

M. Alan Brookhart, PhD
Corresponding author
Email: abrookhart@unc.edu

Version: 2 Date: 10 August 2015

Author’s response to reviews: see over
Reviewer's report

Title: Dynamics of cinacalcet use and biochemical control in hemodialysis patients: A Retrospective New-User Cohort Design

Version: Date: 20 June 2015

Reviewer: Bjorn Meijers

Reviewer's report:

Major compulsory reviewers
Please clarify for non-US based readers what is the nature of the Medicare A-D. This reviewer is not familiar with these terms and while it seems plausible that the conclusions are valid, it is not clear where these conclusions are based upon.

Medicare Parts A through D are government provided insurance programs for the elderly, disabled, and those with certain medical conditions. This sentence has been added to: Page 5, lines 119-121.

What are the odds that patients obtained prescription drug that have not been captured by the used methodology?

As mentioned in the limitations section, it is possible that patients were obtaining medications outside of their Medicare Part D benefit. However, it is likely not a substantial issue, particularly with an expensive medication such as cinacalcet. No revisions were made to the manuscript.

The authors stated in their manuscript that different PTH assays might lead to different absolute values. What type of PTH assay(s) are in use in the different DaVita facilities?

DaVita was contacted concerning whether or not different PTH assays were used during the time frame of our study. DaVita indicated that 1 PTH assay was used for the entire length of follow-up throughout the organization. No revisions were made to the manuscript.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the
statistics.

**Declaration of competing interests:**

I declare that I have no competing interests
Reviewer's report

**Title:** Dynamics of cinacalcet use and biochemical control in hemodialysis patients: A Retrospective New-User Cohort Design

**Version:** 1  **Date:** 5 July 2015

**Reviewer:** Cristina Capusa

**Reviewer's report:**

Major compulsory revisions

1. Information about the used dose of cinacalcet is of great interest because it can influence the magnitude and the time to decrease serum iPTH and calcium, and consequently the discontinuation of therapy. The informative value of the manuscript would be significantly improved by adding this data. However, if there is no possibility to provide it, a clear statement about this lack of data should be added to the study’s limitation discussion.

Information about dose of cinacalcet has been added to the manuscript through the following:

1. Table S7: “Time-dependent cinacalcet dose by follow-up months” has been added to the supplemental material.
2. Most recent dose of cinacalcet has a predictor of discontinuation has been added to tables 2 and S5.

2. The cause of cinacalcet discontinuation (indication from the physician or patient’s self choice) can not be known for sure as per the study design. So, the discussion about patients’ adherence (page 12-13, lines 280-289) seems rather speculative. A comment about this should be added.

The following sentence as been added (lines 281 and 282): Although we cannot know the precise cause of discontinuation, our study is the first to include a large sample size and verify use through Medicare Part D prescription claims, which overcomes many of the possible inaccuracies in start and stop dates.

Minor essential revisions

1. Some studied variables, especially the serum iPTH level, would be better characterized by median (instead of mean). Therefore, I suggest changing the Figure 1 and data from Table 1 accordingly.
Thank you for this suggestion; however, we prefer to report means.

Discretionary revisions

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**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have received speaker fees and financial support for attending scientific meetings from Amgen, Abbvie, Fresenius, Sanofi-Aventis, and Vifor Pharma.