Author’s response to reviews

Title: Medication Utilization Patterns among Type 2 Diabetes Patients Initiating Exenatide BID or Insulin Glargine: A Retrospective Database Study

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Author’s response to reviews: see over
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Editors of BMC Endocrine Disorders:

We are pleased to submit the accompanying revised manuscript, titled, “Medication Utilization Patterns among Type 2 Diabetes Patients Initiating Exenatide BID or Insulin Glargine: A Retrospective Database Study” to BMC Endocrine Disorders for publication consideration. We have addressed the reviewer comments in the accompanying draft. Itemized responses are below. This study used real-world administrative claims data to evaluate treatment modification (i.e., medication switching, intensification, augmentation, or discontinuation) of exenatide or insulin glargine. We believe that this is important information for clinicians and medical decision-makers regarding treatment modification among patients with type 2 diabetes.

As we stated in our original cover letter, each of the authors contributed to the study design and interpretation, as well as the writing and review of the manuscript. All of the authors approve of this manuscript. Below is a summary of the contributions of each author, in addition to providing feedback on manuscript drafts:

- Pawaskar: study design, analysis, writing manuscript
- Bonafede: principal investigator, study design, conduct/data collection, analysis, writing manuscript
- Johnson: study design, conduct/data collection, analysis, writing manuscript
- Fowler: conduct/data collection, analysis, writing manuscript
- Lenhart: conduct/data collection, analysis, writing manuscript
- Hoogwerf: study design, analysis, writing manuscript

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Please do not hesitate to contact me for any additional information or clarification.

Sincerely,

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Reviewer 1:
Authors encouraged to further explore adverse events associated with exenatide.
Tolerability might take several months to accomplish, hence is a possible explanation for longer treatment with exenatide without modification.

This is a valid point and we have added it to our study limitations. Our study followed patients for 18 months after therapy initiation. Unfortunately, requiring patients to be enrolled for longer time periods would have a prohibitive impact on sample size.

Without surrogate markers (HbA1c, fasting glucose), it is unclear how this study describes "real world" use of the agents or that the results are clinically significant.

The lack of clinical markers of disease management (e.g., HbA1c) is a clear limitation of this analysis. That said, the analysis does include a near complete record of patient's healthcare utilization. As we describe in the discussion section, treatment modification has been shown to be a marker of poorer disease management. Since we cannot prove this relationship in the current data source, we have kept our conclusions limited to treatment modification. We believe this is an important outcome as a goal of diabetes management to get patients on aggressive therapy and to maintain stable treatment.

Reviewer 2:
This manuscript has important information. However, there are many limitations to the study which are not report or can be misunderstood by the reader.

Review 2 made several comments directly within the manuscript text. We have addressed these comments in the revised version and highlighted some of the key comments below. We are very appreciative of Reviewer 2's thorough review of the manuscript.

Minor essential revision: do we know if the patient took both doses during each day. Many patients on exenatide BID only take the morning dose. How do we know that both doses were administered?

We have added this as a study limitation. Administrative claims databases contain detailed information on medications received by patients but they do not contain a record of what a patient actually took. We have bolstered our discussion of this in the limitations section.

Minor essential revision: please add more to the limitations of this study. Please include information (or lack of information) on 1) whether the patient's prescriber was a PCP or specialist, 2) the patient had DSME/T and when, 3) was the MTM services provided conducted by a pharmacist? Finally, please add a statement regarding a major limitation of this study was it is data evaluation opposed to patient medication taking behavior assessment.

We have added these items to the limitations section. MTM often doesn't generate an insurance claim and would therefore not appear in the data source used in this analysis. Likewise, the data source does not indicate the prescribing physician. Again, these are all added to the limitations section.