The Use of Claims Databases in Pharmacoeconomic Studies

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Administrative health-care claims databases offer a number of attractive features from which to form the evidence base for conducting pharmacoeconomic studies. These features include the ready availability of data, real-world health-care practice patterns, and potentially large sample sizes and long follow-up. However the ease of access to retrospective data also increase the potential for analytic mining and spurious findings, especially in the absence of prespecified analytic plans. Hence, I believe that the publication of the report of the ISPOR Task Force on Retrospective Databases in this issue represents an important and timely step toward ensuring the quality of published pharmacoeconomic evaluations that use claims data as the basis for their evidence [1].

The goal of the report of the ISPOR Task Force on Retrospective Databases is to provide a checklist that can assist decision makers in evaluating the quality of published studies that use health-related retrospective databases. From the perspective of assessing the quality of pharmacoeconomic studies that are based on evidence from claims data, I believe that the checklist will be useful and of value to decision makers. However, many decision makers may be surprised at the number of published claims based pharmacoeconomic studies that do not provide sufficient answers to many of the questions posed in the guide. As a result, the question remains what steps can be taken to ensure that published claims based pharmacoeconomic studies provide answers to the questions posed in the Checklist? The following suggest a few ideas for consideration and debate.

One idea might be for Value in Health as well as other journals that publish pharmacoconomic studies to consider establishing a submission policy that requires authors of claims-based pharmacoeconomic study manuscripts to submit a standardized checklist that answers the questions in the Report. The checklist could be made available both to the manuscript reviewer and the journal reader. For example, JAMA as well as other medical journals require authors of clinical trial papers to submit alongside their manuscript a completed checklist and flow diagram that follows the requirements set by the Consolidated Standards of Reporting Trials (CONSORT) [2]. Given that the Report’s checklist currently targets decision makers, the format and content may need to be reorganized and expanded to serve as a standardized checklist for authors submitting claims-based pharmacoeconomic study papers. ISPOR might consider leading such an initiative and beginning the dialogue with other journals that publish pharmacoeconomic studies.

A second idea may be for Value in Health to encourage publication of data analysis plans for pharmacoeconomic studies that test hypotheses and base their primary evidence on claims data. One of the most important questions from the Checklist for the decision maker to answer is whether or not a data analysis plan was developed prior to initiating the analysis. The development of a data analysis plan prior to conducting the analysis represents a critical step for ensuring a rigorous research design and increasing the credibility of the published pharmacoeconomic study results. However, given the retrospective nature and ready availability of claims data, it is difficult to ensure that a data analysis plan is developed prior to conducting the initial analysis of the claims data set. Publication of data analysis plans for those pharmacoconomic studies that test hypotheses using claims data may be one mechanism to help ensure this. A model for this can be found in papers on the design of clinical trials published in the journal Controlled Clinical Trials. Sullivan et al. [3], for instance, prespecified as a design paper in Controlled Clinical Trials their design and analytic considerations for determining the cost-effectiveness of early intervention in asthma for a multinational clinical trial. Their rationale for publishing this economic evaluation design paper a priori was to increase the credibility and acceptability of their results upon completion of the trial.

A final idea might be for Value in Health as well as other relevant journals to require that critical validation studies be completed and published prior to or in conjunction with publishing the results of an inferential, claims-based pharmacoeconomic study. An example of such a study is validating that the
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The target population can be accurately identified in the database [4,5]. Another critical validation study is establishing that comparator cohorts accurately represent the pharmacotherapies being compared. For example, do the comparator cohorts accurately represent patients who have newly started a drug, switched to a new therapy, or received combination therapy? To encourage these types of key validation studies, Value in Health might consider issuing a call for papers on validation studies for novel pharmacotherapies that are likely to be evaluated in pharmacoeconomic studies that use claims data as their evidence base. An example of a field of pharmacoeconomic studies that might benefit from this type of validation work is in the evaluation of asthma controller therapies. A variety of inferential pharmacoeconomic studies have been recently published on this class of pharmacotherapies. For some of these studies, however, answers have been sought to questions that are very similar to those questions posed in the Report’s Checklist [6,7]. Publication of these types of validation studies will not only answer some of these questions, but may also motivate analysts to standardize their analytic approaches for specific classes of pharmacotherapies. The standardization of analytic approaches for specific classes of pharmacotherapies can then facilitate replication of analyses across different claims data sets.

In summary, I believe the report of the ISPOR Task Force on Retrospective Databases in this issue will serve as a useful guide for decision makers assessing the quality of published pharmacoeconomic studies that use claims data as the basis for their evidence. The Checklist builds on the recommendations and standards previously published in this journal [8,9]. To ensure that future pharmacoeconomic study publications meet the standards of the Checklist, consideration should be given to what other initiatives might be useful to ensure that researchers provide answers to the Checklist questions in or along with their manuscript submissions.

This commentary provides some ideas for thought and to serve as a starting point. However, given the challenges of implementing ideas such as these, further guidance by a panel such as the ISPOR Task Force on Retrospective Databases would be needed to progress.

References
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