Reviewer’s report

Title: Customized Registry Tool for Tracking Adherence to Clinical Guidelines for Head and Neck Cancers: Protocol for a Pilot Study

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Reviewer: Everardo Delforge Saad

Reviewer's report:

This protocol manuscript describes a planned, pilot observational study to assess the worth of using an information technology (IT) tool for tracking adherence to clinical guidelines in the clinical care of patients with head and neck cancer. The manuscript is well written, and the below comments aim at improving comprehension by the reader.

One key element of the analysis is the comparison based on information collected manually (in the preimplementation period) and information collected using a structured, IT tool. I believe authors should specify how they can ensure that the simple difference in data collection method cannot account for some of the eventual differences in outcomes between periods. For example, can manual collection lead to missing data and exclusion of patients from the preimplementation period in a manner that is non-random, thus introducing bias?

I believe authors need to improve the explanation on "cohorts". Since they say that "patients included in the study will be divided into two separate cohorts: cohort 1, patients with a confirmed diagnosis of head and neck cancer but who have not yet initiated treatment, and cohort 2, patients who have initiated treatment", it isn't clear how it is that "patients who received a diagnosis of head and neck cancer and initiated any treatment will thus be present in both cohorts". Moreover, it is unclear what the relationship is between cohorts (1 and 2) and periods (before and after implementation of the IT tool).

The following paragraph in the manuscript also requites clarification. Authors day that "Patients will be included in the pre-treatment arm if they entered and completed a stage prior to implementation of the tool". Consequently, "patients who started a stage prior to implementation but completed it after implementation will be excluded from analysis for that particular stage", even though "patients who started a stage before implementation but never completed that stage will only be included if they started the stage more than 6 months prior to implementation". Isn't this likely to introduce bias, arguably this bias may go in favor of the IT tool (i.e., by excluding some patients failing to reach milestones)? On a semantic note, I suggest replacing the term "arm", both in the above sentence and in "all patients starting a stage after implementation will be included in the post-treatment arm", by another term, to avoid the connotation of a clinical trial. Also, perhaps the term "pre-treatment" in the first excerpted sentence above is not well suited to the intended meaning.

Can authors please elaborate a bit on which "models controlling for secular trend will be used for the primary and secondary outcomes for each cohort"? Again on a semantic note, this sentence implies that the comparison is between cohorts, when in fact--unless I misunderstand--the comparison is between periods, yet another reason to clarify the terminology.

By "relative hazard", do authors mean "hazard ratio"?
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