Reviewer’s report

Title: Segmented regression analysis should be used to analyse interrupted time series studies

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Reviewer: Robert Penfold

Reviewer’s report:

This manuscript re-evaluates the impact of a collaborative intervention to improve quality in pre-hospital ambulance care for acute myocardial infarction (AMI) and stroke at 11 publicly funded ambulance organizations in England. In particular, the authors add a term to the regression analysis that accounts for the change in slope in the post-implementation period in order to appropriately account for both the overall secular trend and the impact of the intervention on the rate of increase in the outcomes (AMI performance, Stroke performance).

I concur that the original study did not model the impact of the intervention correctly. A main advantage of the ITS approach is the ability to model both the secular trend and change in trend attributable to the intervention.

However, I find the re-analysis incomplete, especially with regard to the AMI performance data. To be fair to the spirit of the original study and increase the educational value of the re-analysis manuscript, I believe that the re-analysis should present additional modifications.

First, the approach should consider the impact of censoring the “ramp-up” period in the all site (aggregate) analysis of AMI performance in order to account for the potential lag in time between implementation of the intervention and when the intervention reached “full-strength”. Such an approach has been used frequently by the Soumerai group and the authors appear to be familiar with their work (see also various papers in NEJM, BMJ, etc with Soumerai as senior author). It is uncommon for quality improvement programs to have an immediate impact on either the intercept or slope and the original authors should have noted this (and specified a “ramp-up” in the model appropriately). Similarly, the authors of the re-analysis should have examined this weakness.

I believe the first 12 observations in the post implementation period should be censored. Technically, this is achieved by setting the first 12 post-intervention observations for the dummy variable “intervention” to missing. I think this
approach will show that there was indeed an inflection in the slope but that this change was delayed until about 3 months after implementation. An alternative approach would be to include 2 index dates with the second index date beginning 3 months after the beginning of the intervention. That is, the segmented model would include 3 time periods: pre-intervention, implementation (12 weeks), and intervention. The possibility of these different specifications should be noted in the current manuscript under consideration. I will leave it up to the authors to decide which approach/result they show in figure 1.

A second consideration is the impact of censoring outliers, modeling them explicitly, and/or smoothing the time series. Power to detect a change in the weekly rate is significantly impacted by variability in the weekly rate. Measurements at weeks 7, 52, and 53 should be censored as part of a sensitivity analysis. A second approach would be to include dummy variables for individual observations (e.g., a dummy coded 1 for week 7 only). An third approach (probably best) is to smooth the rates with a moving average term in the model or aggregate to bi-weekly measurements.

These 4 sensitivity analyses (censoring 12 weeks, specifying 2 index dates, censoring outliers, smoothing time periods) must be performed and included as part of the results and discussion before the commentary is suitable for publication.

Other comments

The tone of the manuscript is not collegial. Remove comments referring to pre-publication history. Remove material about what the original paper did incorrectly. Rephrase all material in terms of ways to improve the analysis and alternate specifications that are likely to yield important new insights and new knowledge. You may find yourself in the very deep gratitude of the original authors if the re-analysis is presented helpfully. Rest assured that you will make a mistake at some time in your career and you will thank yourself for having been kind to your colleagues when it happens to you.

For example:

“In our opinion the authors failed to implement an analytical approach appropriate for an ITS design; therefore, we believe that the authors' conclusions may be misleading.”

Becomes

“We conducted sensitivity analyses under alternative model specifications in
order to better understand the nature and scope of program effects.”
A suggested title for the paper might be something like, “Alternate modeling
approaches yield new insight regarding the implementation of improvements in
pre-hospital ambulance care”. The current title is condescending and
antagonistic.
I am guessing the page limit is 1500 words for a commentary. I suggest
condensing the discussion of stratified analyses (i.e., by site) and removing any
instruction on what the original authors should do.