Inappropriate statistical model and data issues lead to an invalid conclusion.

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Introduction

In a recent article published in JAMA Cardiology, Gupta et al.[1] concluded that, for a Medicare fee-for-service population, hospital readmissions for heart failure declined from the pre-Hospital Readmissions Reduction Program (HRRP) period to the period in which penalties were being assessed for excess readmissions, but that mortality rates increased between these two time periods. However, the article contains several errors and correcting these errors would change the paper's conclusions. There are indications that the data used for the middle time period, after HRRP was implemented but before penalties were imposed, is in error. These problems, combined with an inappropriate statistical model, have resulted in faulty conclusions. Unfortunately, the paper and the supplemental material do not provide enough detail to say exactly what is wrong with the data, so we will list the indicators of problems, explain why these indicators suggest that there are problems with the data and how they have driven the invalid conclusions.

Krumholz et al[2] submitted a letter to the editor commenting on the paper by Gupta and raised issues that overlap with the issues discussed in this paper. They also suggested that random hospital-specific effects should have been considered in the model. This is an important suggestion given that the mix of hospitals may well have changed over time. However, Gupta et al[3] responded and dismissed this suggestion. Krumholz et al did not raise some of the other issues raised here, possibly because of limitations on the length of a letter to the editor.

Data problems

Numbers that are inconsistent between the narrative and the figures

The results report that "the 30-day risk-adjusted readmission rates declined from 20.0% before the HRRP implementation to 18.4% in the HRRP penalty phase." However, Figure 1A shows that in the before implementation phase all the monthly mean 30-day risk-adjusted readmission rates were within 19.2% and 19.7% and in the HRRP penalty phase were within 19.2% and 19.5% so the numbers stated in the results section, being outside of these ranges, are not possible. In fact, Figure 1A shows there was little or no change between the two periods, either in the level or the trends in the data.

The results section also states: "the 30-day risk-adjusted mortality rate increased from 7.2% before the HRRP implementation to 8.6% in the HRRP penalties phase." However, Figure 1B shows all the data points in these two time periods to be between 7.95% and about 8.05%. Again, the results reported are inconsistent with the data shown in the Figure 1.

Change in the variance and level of the data between periods:

The points in Figure 2B lie within a relatively narrow horizontal band at about 8.0% in both the pre-HRRP implementation phase and the HRRP penalty phase but are much more widely scattered in the intermediate phase. In both the pre-HRRP phase and the HRRP penalty phase the range looks to be approximately 7.98 – 8.06, i.e., a range of about 0.08, and in the HRRP implementation phase approximately 7.81 – 8.1, i.e., a range of 0.29 or over 3.5 times the range in the other two periods. This is highly suggestive of data problems in the intermediate phase given that the same data sources were reportedly used in all phases. While it is difficult to determine just by looking at the Figure, it appears that the mean of the data points in the HRRP implementation phase is lower than the mean in the other two phases.

Other indications of potential problems:

The three time periods and the number of cases in each time period are:

Pre-HRRP phase	4.25 years	39,226 cases
HRRP implementation phase	2.5 years	35,222 cases
HRRP penalty phase	2.25 years	40,797 cases

The fact that the last phase is about half the length of the pre-HRRP phase, but has more cases suggests some change in the enrollment practices over time.

The narrative states that data on the transplant status of the hospital was missing in 24.3% of the cases, and that hospital characteristics were not imputed. This means that almost a quarter of the cases would have been dropped from the analysis because of this missing data element – one that should surely have been readily available.

The problems discussed in this section are so obvious they should have been picked up in the peer review process or by the editors.

Statistical model

The statistical model used linear splines with knots at April 1, 2010 and October 1, 2012, the transition dates between the time periods. The knots basically require that the linear splines meet at these date lines. The rationale provided is that "a change in policy is unlikely to lead to a sudden change in outcome level." However, as discussed previously, looking at the data points in Figure 1B it appears there were sudden changes at both these dates, both in the level and the variability of the mortality rates. Given these abrupt changes, requiring the lines to meet at these dates is inappropriate, and results in very misleading conclusions.

Just looking at the lines in Figure 1B one sees that the first spline and last spline are clearly not good fits to the data points within these time periods – the best fit lines would be basically horizontal lines through the middle of the data points. The fitted lines shown in the Figure 1B are being driven by the data in the penalty-free implementation phase, which we previously argued looks very suspect, together with the forcing of the splines to meet at the transition times between the time periods.

Conclusion

In conclusion, the data shown in Figures 1A and 1B do not support the numbers quoted in the results section, and particularly do not support the conclusion that mortality rates increased between the pre-HRRP implementation and HRRP penalty phases. The invalid conclusion is due to a combination of problematic data, particularly in the HRRP-implementation phase, combined with a statistical model that did not fit the data.

References

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