Author's response to reviews

Title: Effect of electronic patient record use on mortality in End Stage Renal Disease, a model chronic disease: retrospective analysis of 8 years of prospectively collected data

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Author's response to reviews: see over
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Melissa Norton, M.D. and Jigisha Patel, MRCP, PhD.,
Editor-in-Chief and Medical Editor
BMC Medical Informatics and Decision Making

Dear Drs. Norton and Patel,

I am pleased to submit the enclosed revised manuscript *Effect of electronic patient record use on mortality in End Stage Renal Disease, a model chronic disease: retrospective analysis of 9 years of prospectively collected data* for publication in BMC Medical Informatics and Decision Making

We appreciate the reviews of Drs. Pan and Ramnarayan which addressed several issues that could clarify points for the reader, and have made revisions in the light of their reviews.

The revisions are:

1. **Extension of the study to include calendar year 2006.**

   After the manuscript was first submitted we analyzed the data for 2006, thereby extending the period of observation to 9 years. We have taken the liberty of including year 2006 in the revised manuscript.

   The favorable results reported in the original submission continued in 2006 as shown in the revised Table 4. Incorporating the additional year reinforced the conclusions in the original manuscript, and did not necessitate any change in the discussion and conclusions. The title of the revised submission reflects the extra year. Tables 1, 2, 3 and 4, Figures 1 and 2, and the relevant text have been changed to incorporate the extra year of data.

2. **Review of Eric Pan**

   The authors claimed that this is the first demonstration of a system of this type having a favorable effect on the outcomes and cost in chronic disease. This is most likely due to the authors searching for impacts of "electronic patient records" where as many researchers would classify a system of this type as a "disease registry." The key distinction between electronic medical records (EMRs) or electronic health records (EHRs) versus disease registry is that of general clinical purpose versus single/multiple disease focus.

   Whereas in the past, many disease registries were simplistic in design and could not be used for patient care, many modern disease registries are similar to the system presented in this paper in that they had been expanded in functionality to enable clinical care and documentation while remaining (single-)disease focused, and therefore still considered "disease registries".

   We believe that the study EPR does in fact differ in certain major ways from “disease registries” which are not, as far as we are aware, designed to enable day-to-day care on-line of patients with chronic disease affecting multiple organ systems. Nevertheless, we again searched PubMed using the term “disease registry” and the MESH keyword mortality. We carefully looked at the 277 articles produced by the search, and concluded that they were in fact not relevant to the manuscript. We have therefore not included any references to disease registries in the revised manuscript.

   Nevertheless we have modified the paragraph below to draw attention to the difference between the study EPR and other systems as raised by Dr. Pan, and in a point raised in his review by Dr. Ramnarayan.

   The patient-centered study EPR captures, stores, and retrieves on-line and without delay all patient-specific medical data from multiple information domains including diagnoses, procedures, symptoms, signs, medications, orders, test results, and dialysis treatments [11,18]. It does so for all venues of care and for
care provided by any caregiver, especially important in dialysis where all patients have multiple systemic
diseases that need repeated evaluation and treatment by multiple providers over many years at a variety of
sites. Unlike disease registries that usually focus on a single disease entity and its assumed complications,
the study EPR is a generalized model of medicine that makes no assumption about future co-morbidities,
complications or outcomes in its data model. On the contrary it captures, stores, and retrieves any or all that
might occur.

3. Review of Padmanabhan Ramnarayan

3.1 General

This suggests the conclusion that some centre-specific features of the units studied may be more
responsible for the findings reported, more than just the use of an EPR.
The differences in the groups (study vs. control) with respect to ethnic origin, incidence of diabetes etc.
may account for some of the differences in mortality rate, an aspect that the authors have not discussed in
detail.

We have added two sentences at the end of the relevant paragraph to add strength to the view that
the reported decrease in mortality was not a center effect.

That mortality of the study population was less than USRDS might be explained by differences between
demographic and comorbid factors of the study and USRDS populations. To test for this possibility we
obtained standardized mortality ratios (SMR) generated by the University of Michigan Kidney
Epidemiology and Cost Center [23]. Since 2001, SMR has been calculated from a Cox model, adjusting for
age, race, ethnicity, gender, diabetes, ESRD duration, patient comorbidities and body mass index at
incidence, and population death rates. SMR trends in 2001-2005 were similar to those in our analysis.
Compared on a year-by-year basis, SMR and the study patient mortality correlated significantly (adjusted r²
= 0.30, p=0.011), suggesting that the decreased mortality in 2001-2006 was not due to differences in
demographic and comorbid factors of the study and USRDS populations. The demographic and comorbid
factors of the population of each Unit, which varied year-to-year almost imperceptibly, cannot explain the
lower mortality observed in each Unit. This supports the view that the lower mortality when compared with
USRDS was not simply due to a center effect.

3.2 Major compulsory revision 1

We have attempted to clarify for the reader the point raised in this review. The relevant revised
paragraphs are:

As might be expected when the number of patients in each unit was relatively small, mortality did vary
substantially year-to-year (Table 4). Nevertheless, save for year 2001 in Unit A, mortality decreased
strikingly in each Unit, from 2000 onward in Unit A, 2001 onward in B, and 2002 onward in C. Considered
by year of EPR deployment, mortality was, with a single exception (Unit A, year 4), lower from year 3
onward.

The effect of year-to-year variation may be expected to be less when the results are recapitulated in periods
of two or more successive years. Mortality for years 1-2, 3-4, and 5-9 of EPR deployment is summarized in
Figure 1. In Unit A, mortality in years 3-4 was 198 per 1000 years, similar to that in years 1-2. In years 5-
9, mortality was 129 per 1000 years, a reduction of 35%. In Unit B, mortality was 44% lower in years 3-4
than in years 1-2, and 49% lower in years 5-8. In Unit C mortality was 36% lower in years 3-4 than in years
1-2, and 32% lower in years 5-7. By contrast, the contemporaneous USRDS mortality remained constant
around 237 per 1000 years

3.2 Major compulsory revision 2

I consulted on the question raised by Dr. Ramnarayan with my colleague C. Ralph Buncher,
Sc.D., Professor of Biostatistics and Epidemiology University of Cincinnati Medical Center. He
advised that, as all data were available, a linear regression analysis was appropriate as a test of
trend. We performed a linear regression analysis, and have added Figure 4 and the following paragraph:

As a test of trend, the mortality data from all 3 Units were then combined and a simple regression analysis of mortality per 1000 years was calculated (Figure 4). This produced a regression of 244.4 – 14.18 per year of study EPR use (adjusted $r^2 = 0.72$, $p=0.0022$). Thus, the mortality decreased by 28 per thousand every two years. It cannot be assumed, however, that this trend will continue with more extended use of the study EPR.

3.2 Minor essential revision

We agree that screen shots will be helpful in enabling readers to contrast the study EPR with their own EPR systems, and have included five screen shots as Figures 1, 2, 6, 7, and 8 for this purpose.

I trust that these revisions clarify the points raised by your reviewers, and want to thank them once again for their insightful comments.

Yours sincerely,

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