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 9 years of prospectively collected data

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Author's response to reviews: see over
October 21, 2007
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 enclose the 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.

Institutional Review Board
As requested, we have documented the IRB approval at the end of the Methods section.

Comments by statistician reviewer
The authors appear to have carried out a comparison of centres against pooled USRDS data using retrospective data, a mix of incident and prevalent patients. The description of patients is not perfect- e.g. table 1. Do all patients have an age of 59.2 years, or is there a spread around a mean value that can be captured by a standard deviation?

- We have added the standard deviation for the age of the study patients, namely 59.2 ± 16.16 years in the second sentence of Results>Patients.

Hence their findings will be affected by the fact that based on case-mix of the prevalent versus incident patients their mortality rates may differ substantially. Vintage as an adjustment variable may or may not fully adjust for it - simply because rates do not remain stable and proportional over years of follow up as subsets of patients in a given age die at different rates. E.g. young diabetics die much faster than other patients, and so patients with a vintage more than 5 years will have less diabetics who, as they are survivors, will have a completely different survival probability when compared to a diabetic starting dialysis.

- As far as we are aware, the United States database for patients with End Stage Renal Disease (USRDS) is one of the only virtually 100% complete databases available for any chronic disease. Because it contains all patients treated by chronic hemodialysis and reports complete data on mortality, it provided a unique standard against which mortality reported in our manuscript could be measured. Nationally, during the period of study the US prevalent hemodialysis patient population grew from ±227,000 in 1998 to ±314,000 in 2005 (USRDS report 2007 Table D7), and the mortality rate changed little (USRDS report 2007 Table H12). As the number of dialysis units grew to accommodate this increase the ratio incident/prevalent can be expected to change little. The dialysis units studied had, with one exception, a constant size and therefore patient treatment capacity during the period of study. As the mortality rate decreased substantially during the period of study, the incident/prevalent ratio can be expected to have decreased, as shown below.
USRDS reports mortality by dialysis vintage in 3 ranks, <2, 2-5, and >5 years (USRDS report 2007 Table H12). As shown below, the mortality in the study units was significantly less than USRDS in all three vintage ranks.

The authors mention findings from a standardised mortality rate calculation in the discussion. These are the most important results and so I wonder whether these should not be described in more detail there rather than in the discussion. I wonder how exactly a Cox model (which conditions out a hazard, does
not estimate a baseline rate as a first step and only gives a log hazard ratio) ends up providing
standardised mortality rates. There must be an additional step of estimation within that approach which is
poorly explained and hard to understand especially for the non-statistical reader and which is not
clarified in the statistical methods section. What was standardised to what - Study populations relative to
USRDS? Their argument that their rates correlate with the standardised mortality rates seems arbitrary -
after all the standardised mortality rates, as far as I guess it, are probably calculated on basis of the same
data - hence it would be worrying to not find a correlations between those two.

• The SMR referred to in the discussion was not calculated by us from our data. Because it is not part
of our results it belongs, we think, in the Discussion rather than the Results. This SMR is calculated
by the University of Michigan Kidney Disease Epidemiology and Cost Center for each dialysis unit in
the United States and reported to individual units on a yearly basis so that they can compare their
performance to national and regional performance. The SMRs referred to in the discussion are those
reported in this way to each of the 3 individual study dialysis units. Details of the methodology used
to calculate the SMR are on the University of Michigan Kidney Disease Epidemiology and Cost
Center website, cited in reference 23. We too would be worried if there was not a correlation between
the two analyses. We included the data from these SMR reports in the Discussion for two reasons:
(1) It was 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.
(2) Because the SMR is widely used and available to the US nephrology community, and we were
advised that its inclusion would help explicate and confirm our results against this widely available
standard.

The analysis presented has however substantially improved from the previous draft and provides some
first important clues. These clues are preliminary, based on retrospective observational data, which are
affected by confounding and bias (inclusion of patients into centres A,B,C, recording of patient records
which was not uniform from starting etc). Randomised studies of such an approach would provide much
more substantive evidence - implementing such studies as a cluster randomised approach across a few
centres is possibly and may be even be funded in a time where any approach to decrease working time of
staff is crucial. Their study is very important in as such now there is a strong argument to implement such
a trial.

• We appreciate the reviewer’s remark that the study is important, and would of course welcome a
future randomized trial. We are, however, less sanguine than the reviewer about the likelihood that
any body would be interested in funding a randomized trial on the scale and for the duration
necessary.

We trust that the manuscript is now suitable for acceptance.

Yours sincerely,

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