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

Authors:

Victor E Pollak (vpollak@migs.com)
Jonathan A Lorch (lorchj@mail.rockefeller.edu)

Version: 5 Date: 25 September 2007

Author's response to reviews: see over
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.

We appreciate the review by Dr. Ramnarayan, and are pleased to note that the revisions made satisfy the points raised in his original review.

**Comments by statistician**

The statistical methodology that was used for the descriptive and comparative analyses (with the USRDS) are not clearly described. If I understood them correctly, they had 3 hospitals, A, B, C. Those had electronic record systems and a continuous update of existing comorbidities and treatment data per patient. In figure 4 they quote mortality rate per patientyear suggests that they used rates to describe their data, but not which analytic method they used to compare the rates, nor whether they took account of the underlying case-mix of the cohort, nor whether they were sure that their statistical model was fitting the data appropriately.

The following paragraph has been added to the methods (page 9):

Mortality per 1000 patient years was calculated for each individual study unit in each calendar year, as is done by USRDS, by dividing the number of deaths in each individual year by the total time in years that the patients were treated by HD in that calendar year, and multiplying by 1000.

We appreciate having this omission brought to our attention.

Mortality per 1000 patient years was calculated for each individual study unit in each calendar year, as indicated above and is reported in Table 4. Figure 4 presents the same data, recalculated for years 1-2, 3-4, and 5-9 of the study EPR use. At the same time, the USRDS mortality (given in Table 4 but not indicated on Figure 4) varied between 229 and 241 per 1000 years.

We believe that the revised manuscript details this explicitly. Both Dr. Ramnarayan and my colleague C. Ralph Buncher, Sc.D., Professor of Biostatistics and Epidemiology University of Cincinnati Medical Center, appear to concur with our view.

*If this was an epidemiological comparison then I would want to see description of the incident/prevalent cohorts in terms of sampling, representativeness for the patient population on dialysis in that area, age/sex/ethnicity profile, reasons to end up on RRT, social standing, comorbidities - compared to USRDS data on incident/prevalent patients in similar period of time. -description of length of follow up, amount of censoring, how many were transplanted etc.-comparative analysis (typically survival type analysis) of the cohorts. For example calculation of standardised mortality rates, or Poisson regression; or, if hazard not constant over time for example Cox regression, especially to adjust for case-mix (well, at least diabetic nephropathy at baseline) to see to which extent confounding by case selection onto those hospitals A, B, C may explain the better outcome.*

The manuscript is not, in the conventional sense an epidemiological comparison. Nevertheless the patients treated in the three study units differed in relatively minor respects from the national (USRDS) data as detailed in Figure 1 and on page 9. Data on standardized mortality, available for years 2001-2006, are included in the discussion on page 13:

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 $r^2 = 0.30, p=0.011$), 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.

**Changes in text made by the authors**

The latest USRDS data were published very recently, and since the last submission of the manuscript. Reference 12 has been updated, and we have made the following changes to reflect availability of the 2005 USRDS data:

1. USRDS data in Table 1 now reflect 1998-2005, rather than 1998-2004. The changes for patient characteristics have been made and are minor. The number of patients (line 1) in the previous version was incorrect. The revision reflects the correct number of patients for 1998-2005.
2. The USRDS mean age and mortality rate for 2005 are now included in Table 4.
3. Table 5 now reflects the study unit and USRDS data for 2004 and 2005 combined rather than for 2004 only.
4. The section on staff (page 12) has been rewritten.
5. Minor changes have been made elsewhere in the text:
   1. Page 1, second last line .Clinical staffing was 25% fewer
   2. Page 23, figure 5 .Data from all 3 dialysis units combined were used to analyze regression of mortality per 1000 patient years of study
      electronic patient record (EPR) use.

It appears to us that the points raised by the statistician are in fact adequately explicated in the manuscript, as Dr. Ramnarayan and Dr. Buncher agree. We trust that the manuscript is now suitable for acceptance.

Yours sincerely,

Victor E. Pollak, M.D., FACP, FRCPE
Emeritus Professor of Internal Medicine, University of Cincinnati
Professor of Clinical Medicine, University of Colorado
Senior Vice-President & Medical Director, MIQS, Inc.