Nephrol Dial Transplant (2008) 23: 3227–3233
doi: 10.1093/ndt/gfn195
Advance Access publication 18 April 2008

Original Article

NDT
Nephrology Dialysis Transplantation

A practice-related risk score (PRS): a DOPPS-derived aggregate quality index for haemodialysis facilities

David C. Mendelssohn[1], Ronald L. Pisoni[2], Charlotte J. Arrington[2], Karen E. Yeates[3], Martine Leblanc[4], Clement Deziel[5], Takashi Akiba[6], Mahesh Krishnan[7], Shunichi Fukuhara[8], Norbert Lameire[9], Friedrich K. Port[2] and Robert A. Wolfe[2]

[1]Humber River Regional Hospital, Weston, Ontario, Canada, [2]Arbor Research Collaborative for Health, Ann Arbor, MI, USA, [3]Queen's University, Kingston, Ontario, [4]Maisonneuve Rosemont Hospital, University of Montreal, Montreal, [5]Hôpital du Sacré-Cœur de Montréal, Université de Montréal, Québec, Canada, [6]Toyko Women's Medical University, Tokyo, Japan, [7]Amgen, Inc., Thousand Oaks, CA, USA, [8]Kyoto University Graduate School of Medicine and Public Health, Kyoto, Japan and [9]Ghent University Hospital, Ghent, Belgium

Abstract

Background. The Dialysis Outcomes and Practice Patterns Study (DOPPS) database was used to develop and validate a practice-related risk score (PRS) based on modifiable practices to help facilities assess potential areas for improving patient care.

Methods. Relative risks (RRs) from a multivariable Cox mortality model, based on observational haemodialysis (HD) patient data from DOPPS I (1996–2001, seven countries), were used. The four practices were the percent of patients with Kt/V $\geq$1.2, haemoglobin $\geq$11 g/dl (110 g/l), albumin $\geq$4.0 g/dl (40g/l) and catheter use, and were significantly related to mortality when modelled together. DOPPS II data (2002–2004, 12 countries) were used to evaluate the relationship between PRS and mortality risk using Cox regression.

Results. For facilities in DOPPS I and II, changes in PRS over time were significantly correlated with changes in the standardized mortality ratio (SMR). The PRS ranged from 1.0 to 2.1. Overall, the adjusted RR of death was 1.05 per 0.1 points higher PRS ($P < 0.0001$). For facilities in both DOPPS I and II ($N = 119$), a 0.2 decrease in PRS was associated with a 0.19 decrease in SMR ($P = 0.005$). On average, facilities that improved PRS practices showed significantly reduced mortality over the same time frame.

Conclusions. The PRS assesses modifiable HD practices that are linked to improved patient survival. Further refinements might lead to improvements in the PRS and will address regional variations in the PRS/mortality relationship.

Keywords: dialysis outcomes and practice patterns study; haemodialysis; patient risk score; survival; quality index

Introduction

Translation of recommendations from clinical practice guidelines into clinical practice is a challenge, both for a facility medical director or an individual clinical nephrologist. The principles of continuous quality improvement (CQI) are increasingly understood by the renal community, but barriers prevent widespread utilization of this powerful methodology. Variability in many aspects of haemodialysis (HD) care from facility to facility, and from clinician to clinician, remains an issue, even following the dissemination of clinical practice guidelines.

Clinical performance measures have evolved as a way to monitor the implementation of key clinical practice recommendations. Most modern HD units can report on how they perform on key indicators such as dialysis dose and haemoglobin levels. While these indicators show improvement over time and are useful, they are unidimensional and may not reflect the overall performance of a dialysis unit [1].

Recently, the DaVita dialysis chain in the United States developed a dialysis quality index (DQI) that it uses to promote CQI across its facilities [2,3]. This aggregate index includes seven variables that are weighted and then summed to create a 100-point scale. Facilities are tracked on a quarterly basis, so that both internal and chain-wide comparisons can be made. Their preliminary data show that improvements in the DQI are associated with a decrease of standardized mortality ratios (SMR). Furthermore, the DQI allows for the identification of poorly performing facilities that require external assistance with quality improvement. It also creates a 'culture of quality' that serves as a basis for pride and rewards for a facility's quality improvement activities. The weighting of the formulas was based on expert opinion. The former Renal Care Group developed a similar index that was based on 10 clinical quality indicators and patient satisfaction measures, aggregated to derive a Composite Facility Score (R. Hakim, personal communication).

Correspondence and offprint requests to: David C. Mendelssohn, University of Toronto, 200 Church St., Room 2024, Weston, Ontario, M5N 1N8, Canada. Tel: +1-416-243-4368; Fax: +1-416-243-4421; E-mail: dmendelssohn@hrrh.on.ca

The concept and potential usefulness of an aggregate index like the DQI has considerable merit. However, the DaVita formula includes the SMR as a minor component of the index. Given that the index is intended to predict SMR, the mathematics are flawed if SMR is included in both sides of the equation. Additionally, an empirical approach to the weighting of variables would be preferred.

Recently, a group of Canadian nephrologists with an interest in CQI has been working together to consider new approaches to CQI, including the development of an aggregate index for HD facilities. A collaboration with the Arbor Research Collaborative for Health, who established the prospective Dialysis Outcomes and Practice Patterns Study (DOPPS) database, provided a rich resource to help create and validate an aggregate quality index. This manuscript describes the process to date that has led to the development of an outcome-driven aggregate HD quality index that we call the practice-related risk score (PRS). A major objective of this was to determine whether we could correlate improvements in practice with improvements in patient longevity at the facility level.

Methods

Data sources

DOPPS is a prospective, observational study of adult HD patients with the present analysis based on data from seven countries participating in DOPPS I and 12 countries from DOPPS II. Study inclusion criteria required that patients were considered by their physicians to require chronic, maintenance HD (typically at least two to three HD treatments per week), but allowed for the therapies of haemodiafiltration and haemofiltration. The first phase of the study (DOPPS I, 1996–2001) collected data from 308 facilities in France, Germany, Italy, Japan, Spain, the United Kingdom and the United States. The second phase (DOPPS II, 2002–2004) of 320 facilities added an additional five countries to the original seven: Australia, Belgium, Canada, New Zealand and Sweden. A stratified random sample of dialysis facilities was selected in each country, and a census of prevalent HD patients was used to randomly select 20–40 patients at each facility. Patients participating in clinical trials were not excluded from eligibility for DOPPS. Details of the study methodology have been described previously [4,5].

The patient haemoglobin, serum albumin, pre-and post-dialysis blood urea nitrogen or blood urea values used in these analyses were based upon a patient's most recent value measured on or before the study entry date. For the majority of patients, these values were measured within 30 days of the study enrolment date since all of the laboratory measurements are routinely tested for the majority of HD patients. To minimize the effects of residual renal function on the relationship between Kt/V and mortality, Kt/V calculations were restricted to patients having end-stage renal disease (ESRD) >1 year as only a small fraction of these patients ($<5\%$) had significant residual renal function after having ESRD for 1 year or longer. Catheter use was calculated based upon the type of vascular access a patient was using on the date of study entry.

Statistical analyses

The PRS was developed based upon several largely modifiable facility HD practices for which The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines currently exist. A multivariable Cox mortality model was constructed using a prevalent cross-section of DOPPS I data ($n = 6665$) using different levels of four facility practices. Relative risks from this model were then used as the score for each level, a method that used empirical weighting of the relative mortality risk associated with each level. The best-practice level in each group served as the reference and therefore had a score of 1.0 for that practice. The four practices used for developing the PRS were facility-based percent of patients with Kt/V $\geq$1.2, haemoglobin $\geq$11 g/dl (110 g/l), albumin $\geq$4.0 g/dl (40 g/l) and catheter use. These factors were selected because each was significantly related to mortality when included together in the Cox model. Differences in the method of albumin measurement were not considered in this analysis. Other factors tested in the model but not found to be significant included serum calcium, serum phosphorus, calcium–phosphorus product, iPTH, treatment time, shortened treatments, multivitamin use and Pneumovax vaccination. Facility-level practices were based on a prevalent cross-section of patients and restricted to facilities with at least six patients with available data for each indicator.

The scores for each practice were then multiplied to obtain the PRS. For interpretation, facilities with a PRS of 1.30 have on average a 30% higher risk of mortality relative to patients in facilities with good practice for all four facility measures. A facility in the best category for all four practices would have a score of 1.0.

DOPPS II data ($n = 7826$) were then used to assess the relationship between the PRS and mortality risk using Cox regression. All models were adjusted for age, sex, black race, years on dialysis, 14 summary comorbid conditions [coronary artery disease, congestive heart failure, other cardiac disease, hypertension, cerebrovascular disease, peripheral vascular disease, diabetes, lung disease, cancer (excluding skin), HIV/AIDS, gastrointestinal bleeding, neurologic disease, psychiatric disease and recurrent cellulitis], unit type, region and accounted for facility clustering.

For those facilities participating in both DOPPS I and II, an SMR adjusted for the above factors was constructed to correlate the change in SMR from DOPPS I to II with the corresponding change in PRS. Expected deaths for the comorbidity-adjusted SMR were estimated based on a Cox mortality model using data from both DOPPS I and II. The PRS was calculated at the start of DOPPS I and the start of DOPPS II, and the SMR was based on the first 18 months of follow-up from each phase in order to capture only the time frame nearest to the defined PRS in case facility practices changed over time. The PRS and SMR values calculated for facilities participating in DOPPS I and II were based upon a prevalent cross-section of study patients who were randomly selected for participation at the start of DOPPS I and the start of DOPPS II. These random selections were independent of one another. Thus, each random selection provides a representative sample of facility patients in DOPPS I and DOPPS II. Patients could

only be included in both prevalent cross-sections if receiving chronic HD in the facility at both time points and if they were randomly chosen at both time points.

All statistical analyses were performed using SAS version 9.1 (SAS Institute, Cary, NC, USA).

Results

Concepts for development of the PRS

The process of developing the PRS using DOPPS data was based upon several key concepts: [1] Cox regression models would be used to estimate the mortality risks associated with simultaneously achieving certain levels of 'good practice' for various HD practices within a facility and that the PRS would be calculated from these Cox regression models by multiplying the relative risks of mortality for each of the practices within the same model; [2] a facility's achievement level for a particular HD practice would be based upon the percentage of facility patients in a prevalent cross-section attaining a pre-defined cut-point for 'good practice'; [3] cut-points for 'good practice' (e.g. percent of patients with a single pool Kt/V $\geq$1.2) would be based upon the current KDOQI guidelines as much as possible; [4] differences in patient case-mix between facilities would be accounted for in the mortality models through extensive adjustment for patient demographics and comorbidities; [5] a facility's PRS would be easily interpretable as indicating the magnitude of additional risk for the facility's modelled practices compared to facilities having the best level of practice in all modelled practice areas; [6] for a facility, an estimate of mortality risk and level of achievement could be provided for each facility practice contributing to the PRS, and; [7] the PRS would be significantly related to mortality risk when facilities are grouped together by PRS scores; for this purpose, the construction of the PRS would be performed with DOPPS I data and testing of the PRS/mortality relationship would be performed with DOPPS II data. An important feature was an evaluation of a correlation of changes in PRS over time with changes in mortality risk.

Facility practices and relationship with mortality risk

Applying the above strategy for developing the PRS, approximately 10 facility practices were initially investigated to determine their relationship with mortality risk of facility patients. Practices and cut-points included the percent of facility patients with single-pool Kt/V $\geq$1.2, haemoglobin $\geq$11 g/dl (110 g/l), serum albumin $\geq$4.0 g/dl (40 g/l), a central venous catheter as a vascular access, serum phosphorus concentration between 3.5 and 5.5 mg/dl (1.1 and 1.8 mmol/l), serum calcium concentration between 8.4 and 9.5 mg/dl (2.1 and 2.4 mmol/l), calcium–phosphorus product, treatment time, shortened treatments, multivitamin use and Pneumovax vaccination use.

Initially, the relationship between mortality risk and categories of each facility practice were examined in models adjusted for patient demographic and comorbid factors but without adjustment for other facility practices. These analyses were helpful for (a) indicating whether a given facility practice was significantly associated with mortality risk and (b) understanding the shape of the relationship of mortality risk with different levels of a given facility practice. If the facility practice was not significantly associated with mortality risk in these analyses, the practice would be excluded from further consideration for use in constructing the PRS. On the other hand, facility practices which were significantly related to mortality risk in these individual facility practice models were included together in the final Cox mortality model which was used to determine the mortality risks associated with simultaneously achieving different levels of 'good practice' for various HD practices within a facility. This process resulted in four facility practices displaying a significant relationship with mortality when modelled simultaneously. The four practices were percent of facility patients with a single-pool Kt/V $\geq$1.2, haemoglobin $\geq$11 g/dl (110 g/l), serum albumin $\geq$4.0 g/dl (40 g/l) and using central venous catheters as a vascular access (Table 1). The shape of the relationship of each of these facility practices with mortality was examined by arbitrarily using five categories of target achievement over the range from 0 to 100% in increments of 20%. For some of these facility practices, categories were combined into a single group if the relationship with mortality was similar across the categories or if the sample size in one particular category was too small.

Table 1. Facility measures included in PRS

% patients with Kt/V $\geq$1.2
% patients with Hgb $\geq$11 g/dl
% patients with albumin $\geq$4.0 g/dl
% patients with catheters

Based on a prevalent cross-section of DOPPS I patients. Also tested but not significant: serum calcium, serum phosphorus, calcium–phosphorus product, treatment time, shortened treatments, multivitamin use and vaccination with Pneumovax.

For the four facility practices, Table 2 shows the relative risk of mortality associated with each category of the given facility practice. Thus, we see for the facility practice of attaining a single-pool Kt/V $\geq$1.2 that facilities in which $\leq$40% of patients achieve this target, a 46% higher risk of death (RR = 1.46, n = 15 facilities) is seen compared with the 113 facilities in which 80–100% of patients achieve this target for dialysis dose. The RRs shown in Table 2 are based on DOPPS I data, stratified by the seven countries participating in DOPPS I, and adjusted for the factors as indicated. Therefore, the RRs shown in Table 2 represent the average effect across countries.

Calculation of the PRS

The PRS is easily calculated by multiplication of the RRs corresponding to a facility's level of practice in each of the four facility practice areas shown in Table 2. The example in Table 2 shows a facility having an RR = 1.33 for mortality risk due to having 40–60% of patients with Kt/V $\geq$1.2, RR = 1.00 for having >60% of patients with Hgb $\geq$11 g/dl (110 g/l), RR = 1.12 for having 10–20% of patients

Table 2. Calculating PRS based on facility model results

Facility factor	N facilities	RR* death	Example facility
Kt/V >1.2, 0–40%	15	1.46	
Kt/V >1.2, 40–60%	49	1.33	a
Kt/V >1.2, 60–80%	99	1.06	
Kt/V >1.2, 80–100%	113	1.00	
Hgb >11 g/dl, 0–20%	67	1.26	
Hgb >11 g/dl, 20–60%	191	1.18	
Hgb >11 g/dl, 60–100%	47	1.00	a
Catheter use, 20–100%	61	1.13	
Catheter use, 10–20%	63	1.12	a
Catheter use, 0–10%	182	1.00	
Albumin >4.0 g/dl, 0–20%	68	1.18	
Albumin >4.0 g/dl, 20–40%	87	1.06	
Albumin >4.0 g/dl, 40–100%	127	1.00	a

Example facility: PRS score = 1.33 * 1.00 * 1.12 * 1.00 = 1.49.
*RRs based on the Cox model adjusting simultaneously for all four facility factors and patient age, gender, black race, years with ESRD, 13 summary comorbid conditions and unit type; analysis was stratified by country, and accounted for facility clustering effects. The example in the bottom row shows how the PRS score is calculated for a hypothetical facility having the categories of HD practice noted with an 'a' in the table, and for which the RRs of death pertaining to these categories are then multiplied by one another to yield the PRS score.

using a catheter and RR = 1.00 for having >40% of patients with a serum albumin ≥4.0 g/dl (40 g/l). The PRS for this facility is obtained by multiplying these four RRs as 1.33*1.00*1.12*1.00 = 1.49. This PRS of 1.49 can be readily interpreted that patients within facilities with this type of practice have a 49% higher mortality risk on average compared to patients in facilities having the best level of practice for all four practices areas. This interpretation is provided from the design feature of basing the PRS upon RRs that are empirically derived from the simultaneous facility-level mortality models. Based upon the RRs shown in Table 2, the PRS calculated in this manner can range from a value of 1.0 (facilities with the best levels for all four measures) to the highest possible value of 2.45 (calculated from 1.46*1.26*1.13*1.18).

Validation of PRS: Relationship between PRS and mortality risk in DOPPS II data

The PRS was constructed using DOPPS I data collected in seven countries from 1996 to 2001. The relationship between PRS and mortality risk was evaluated using DOPPS II data collected in 12 countries from 2002 to 2004. As shown in Figure 1, PRS as a continuous variable was strongly related to mortality risk in the DOPPS II patient sample, with a 5% higher mortality risk observed for every 0.1 point higher PRS score ($P < 0.0001$). For these analyses, 282 facilities in DOPPS II displayed PRS ranging from a low value of 1.0 to a high value of 2.1. When these facility PRS were categorized into quartiles of the score, mortality risk was seen to be higher with each higher quartile of the PRS score, with a plateau in the two highest categories. Since the PRS is composed of multiple facility practices with varying contributions of each practice to the score, it can be expected that the relationship between PRS and mortality risk will not necessarily be linear across the range of PRS scores. Patients dialyzing in facilities with the highest PRS quartile (PRS from 1.42 to 2.1) had a 41% higher mortality risk on average ($P < 0.0001$) compared with patients treated in facilities having a PRS of 1.0–1.19 (the lowest PRS quartile). All of these analyses were adjusted for patient demographics, comorbidities, unit type and were stratified by country. The DOPPS I study design allowed for the stability of facility PRS to be examined. In comparing the PRS score for a facility at the time of study entry and 1 year later, the median percent change in facility PRS over this 1-year time period was 0.0% (25th percentile = −3.7%, 75th percentile = 6.4%), indicating the relative stable nature of the PRS score for many facilities over this period of analysis.

A sensitivity analysis was performed to determine the relationship of PRS with mortality by three regions in the DOPPS: North America, Europe + Australia/New Zealand and Japan. The PRS was most strongly related to mortality in North America with a 6% higher mortality risk for every 0.1 higher PRS ($P < 0.0001$). The PRS/mortality relationship was slightly weaker (RR = 1.05 per 0.1 higher PRS, $P = 0.008$) in the Europe + Australia/New Zealand sample. However, the composition of the PRS does not appear to be informative regarding mortality risk in Japan (RR = 0.98 per 0.1 higher PRS, $P = 0.62$).

Does a change in facility PRS over time correlate with temporal changes in facility mortality risk?

A PRS may serve as an instrument for dialysis facilities in gauging improvements in certain HD practices over time. Longitudinal DOPPS data provide the opportunity for investigating whether changes in a facility's PRS over time are significantly related to mortality risk over the same time period. Thus, we hypothesized that if dialysis facilities improved their PRS by improving dialysis dose, anaemia management, vascular access use and/or nutritional status of their patients from DOPPS I to II, while keeping all else constant, then would show a significantly reduced mortality risk over the time period.

Analyses had to be restricted to the 124 dialysis units participating in both DOPPS I and II. As indicated by the schematic diagram in Figure 2, for each facility a PRS1 was calculated based upon a prevalent cross-section of patients at the start of DOPPS I, and a PRS2 was calculated based upon a prevalent cross-section of patients at the start of DOPPS II. The ΔPRS corresponds to the difference in PRS2 − PRS1. In order to assess each facility's mortality risk in DOPPS I versus DOPPS II, an SMR was calculated for each facility for the first 1.5 years of the study follow-up in DOPPS I and DOPPS II, yielding an SMR1 and SMR2, respectively. The ΔSMR corresponds to the difference in SMR2-SMR1. Approximately 60% of facilities improved their PRS from DOPPS I to DOPPS II while the remaining facilities showed either a stable PRS or a decline in performance.

Based on regression analysis, Figure 3 shows that a 0.2-point decrease in the facility PRS from DOPPS I to II was significantly associated with a 0.19-point decrease

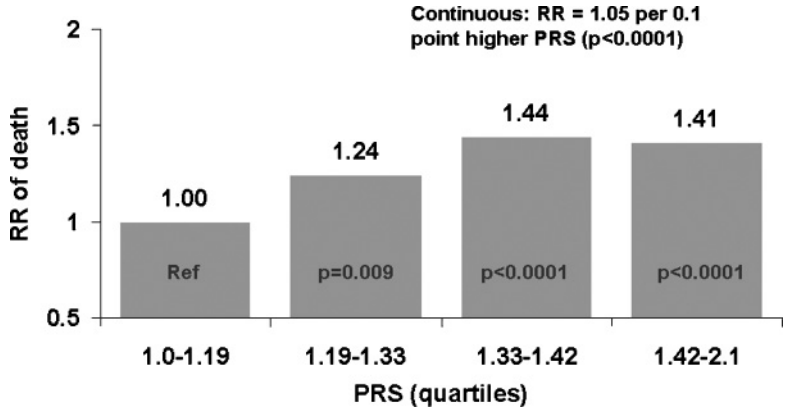

Fig. 1. Adjusted relative risk of death in DOPPS II HD patients, by quartiles of the practice-related risk score (PRS). The PRS was calculated for each facility participating in DOPPS II based upon the RR of death indicated in Table 2 for different practice levels, and the percentages of facility patients in DOPPS II with a Kt/V $\geq$1.2, Hgb $\geq$11 g/dl, serum albumin $\geq$4.0 g/dl and using a catheter for vascular access. These percentages were calculated from the prevalent cross-section of study patients treated in the facility at the time of initiating DOPPS II data collection. Each facility patient in this prevalent cross-section was assigned the facility's PRS value. The relationship between patient mortality risk and PRS quartile was analysed using Cox regression models, adjusting for age, gender, black versus non-black race, years with end-stage renal disease, 13 summary comorbid conditions and unit type ($n = 7826$). Models were stratified by country, and accounted for facility clustering effects. The inset indicates the relationship between mortality risk and PRS as a continuous variable.

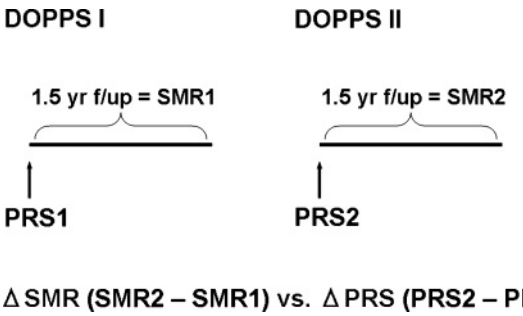

Fig. 2. Design of the facility-based delta–delta analysis method. Separate PRS values were calculated at the beginning of DOPPS I (PRS1) and DOPPS II (PRS2) for each facility. A facility's PRS value at each time point was calculated as described in Table 2 based upon a prevalent cross-section of patients in the facility at the given time point. The delta PRS was calculated as the difference of PRS2 − PRS1. Similarly, for each facility an SMR was calculated for the 1.5 years of the study follow-up after the beginning of each study phase to provide an SMR1 for DOPPS I and an SMR2 for DOPPS II. The delta SMR was calculated as the difference of SMR2 − SMR1. Linear regression analysis was then applied to determine the relationship between ΔSMR and ΔPRS. SMRs were adjusted for numerous patient characteristics and comorbidities as described in the Methods section.

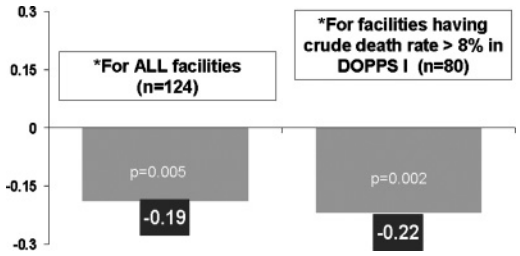

Fig. 3. Delta–delta analysis: average change in SMR per 0.2 point decrease in PRS from DOPPS I to DOPPS II. Linear regression was used to examine the relationship between ΔPRS and ΔSMR. Data were available from 124 facilities participating in both DOPPS I and II for which ΔPRS and ΔSMR could be calculated. A sensitivity analysis was performed to examine the relationship between ΔPRS and ΔSMR when restricted to facilities having a crude death rate $\geq$8% in DOPPS I ($n = 80$).

in the facility SMR ($P = 0.005$). This is equivalent to a decline in facility SMR from 1.0 to 0.81 or as a reduction from 18 to 15 annual deaths in a facility treating 100 chronic HD patients. Analyses using a shorter mortality follow-up time of 1 year showed a very similar relationship between ΔPRS and ΔSMR as seen in the models using 1.5 years of mortality follow-up time, although with less precision due to the substantially shorter follow-up time.

A sensitivity analysis was performed to determine if the relationship between facility ΔPRS and facility ΔSMR differed if facilities with a very low mortality risk in DOPPS I ($\leq$8 deaths per 100 patient-years) were excluded. This restricted analysis of 80 facilities indicated an even stronger relationship between ΔPRS and ΔSMR with a 0.2-point decrease in the facility PRS from DOPPS I to II being associated with a 0.22-point decrease in the facility SMR ($P = 0.002$) (e.g. 22 versus 17 annual deaths per 100 patients). Overall, these 'delta–delta' results indicate the ability of the PRS to serve as an aggregate index of improvements in HD practices, which are significantly related to improvements in patient survival.

Discussion

Results from a prospective, observational study like the DOPPS are considered to be hypothesis generating and often raise questions that are best answered by randomized controlled trials. One limitation of observational studies based on patient-level data is the existence of unmeasured confounding which may play an integral role in the relationship seen between a patient-related factor and an outcome. By adjusting analyses for many potential confounding

elements, the risk that the observed relationship between the measured factor and an outcome is due to confounding can be reduced, but not completely eliminated. However, an important methodology upon which the DOPPS study design is based is to analyse outcomes in relationship to facility practices rather than patient-level factors as a means to further reduce the confounding by indication that is inherent in patient-level analyses, and thereby provide a greater opportunity to observe the true relationship between a practice and outcome. The present study shows a strong association of facility practices with facility mortality risk with full adjustment for case-mix as a refined SMR.

Furthermore, an additional methodology used in the present work, which we refer to as the facility-based delta–delta analysis, serves as another important tool for further reducing confounding. The correlation of facility-level changes in practice (ΔPRS) with facility-level changes in outcomes (ΔSMR), the delta–delta analysis is a major validation of the DOPPS approach since it shows that positive interventions to improve several intermediate outcomes are associated with improvements in SMR. This finding brings us closer to suggesting causality, as it simulates a randomized controlled trial of an experiment in which some facilities implement a change in practice whereas other facilities do not and then this change in practice is correlated with changes in facility outcomes such as SMR. Since each facility serves as its own control, this methodology provides a powerful means within an observational study setting to account for patient-level confounding, particularly if the time period is relatively short over which these facility practice changes are monitored.

It is possible that the mechanisms that lead from reducing PRS scores over time to better hard outcomes are both direct and indirect. In other words, some of the benefit may accrue directly from improving performance that focuses directly on guideline targets. In addition, some of the benefit may relate to other improvements in care that are made when a culture of quality and a systematic approach to quality improvement is implemented in HD facilities. The present study design does not allow for quantification of the relative contribution of these direct and indirect effects.

The PRS is intentionally based upon clinically important and modifiable practice patterns. Nonetheless, there is a view that both low haemoglobin and low albumin levels reflect serious illness with a poor prognosis, and that efforts to increase them in isolation may not lead to the expected improvement in prognosis. Certainly, for haemoglobin, there are easily implemented, clinical manoeuvres that can be applied to achieve partial correction. However, those who do not respond and who have a high ESA/Hb ratio remain at high risk of mortality [6].

The powerful negative predictive effect of albumin on prognosis in HD patients has been recognized since 1992 [7]. Despite this, very little research effort has gone into developing robust clinical approaches to albumin correction. Indeed, because serum albumin is inherently difficult to change with current treatment paradigms in HD, we have empirically tried to remove it from the PRS formula. However, a three-variable model without albumin was not as robust. Similarly, the replacement of the variable of albumin with other variables such as serum phosphate, serum calcium, calcium–phosphorus product, iPTH, treatment time and skipped treatments was associated with a worse performance for the score. Furthermore, models that used five and six variables, models with adjustments of the selected optimal ranges and models with weighting of variables also did not improve the score. Although higher serum calcium–phosphorus product levels and shorter treatment time are known to be associated with higher HD patient mortality risks, the lack of a significant contribution of these factors at the facility level to the PRS in the current work may be due to (a) part of their effects explained by other treatment practices already included in the PRS or (b) a narrower range of practice variability across facilities coupled with a small mortality effect size across this range of practice variability. While we recognize that inclusion of albumin in the PRS may be viewed by some as a limitation, we hope that these results will stimulate new research initiatives to achieve better albumin results. These might include longer HD treatment times and/or daily HD. We suggest that approaches involving a direct focus on the manipulation of albumin, along with indirect efforts to correct the underlying inflammation and other factors that cause the low albumin (and low haemoglobin in ESA resistant patients), must be explored.

One caveat when applying the PRS within a given facility is that mortality associations are averaged across many DOPPS units and may not reflect the mortality experience at a particular facility. This study clearly suggests that no matter what baseline demographics, comorbidity or SMR are observed in a given facility, an improvement in PRS is likely to be associated with an improvement in patient survival within that facility.

The lack of applicability of the PRS among Japanese patients is not well understood. It may be due to the fact that catheter use is low ($<5\%$) in Japan in nearly all dialysis units, and so in Japan there is little variability regarding this component of the PRS. Less variation is also seen in the haemoglobin component, with a consistently lower percentage of patients achieving haemoglobin levels of >11 g/dl (110 g/l) compared to other countries. Further investigations are needed to understand these regional variations in the relationship between PRS and mortality for future enhancements of the PRS. Sensitivity analyses indicate that overall results do not vary greatly when Japan is excluded from the analysis. Additionally, the delta–delta relationship holds for Japan, though the relationship is only marginally significant (0.09). This may be due to the smaller sample size of the country-specific analysis.

Wolfe *et al*. have previously applied this facility-based delta–delta analysis methodology to a US national database of 2858 facilities, to show that changes in adherence to guidelines for haemoglobin and dialysis dose over a 4-year time period was associated with changes in mortality risk [1]. Facilities in the highest tertiles of improvement of both urea reduction ratio and haematocrit $\geq 33\%$ had the biggest improvement in mortality outcomes. In other words, simultaneous changes in two key practices were associated, each independently, with an impact on survival. This current study is important because it confirms those observations

in a different, international database, and it extends them to include other practice patterns. Several patient-based analyses agree with an association between guideline targets achieved and patient survival, but such studies are more prone to confounding than facility-based analyses [8–11].

The need for an aggregate index has been recognized by the hospital sector for many years. Hospitals track not only key clinical performance measures, but also include patient and staff satisfaction and financial indicators in what has become known as a hospital-balanced scorecard. The PRS can be considered a step along a similar pathway towards a broader and more comprehensive attempt to describe the quality of a single or group of HD facilities. In 2006, there were no dialysis-specific, standardized, industry-wide instruments to measure patient and staff satisfaction. We encourage the development of these tools, and we anticipate that the PRS might be modified to include them in the future.

Some facilities treat older or sicker patients. For this reason, comparisons of PRS must include many other standard indicators such as age, diabetes and other factors to allow comparisons of practices. At present, we recommend that the use of the PRS be limited to internal facility purposes, at least until further validation and implementation studies are completed. Furthermore, this work supports the achievement of KDOQI targets and should not be extrapolated to suggest that an increased benefit might accrue if KDOQI targets were exceeded. Finally, DOPPS analyses are based upon results for HD patients only and therefore are not generalizable to peritoneal dialysis patients.

In conclusion, the PRS assesses four key modifiable HD practices that are linked to improved patient survival. The mathematical calculations are simple and the data required are likely to be available in most HD facilities. On average, facilities that improved their PRS practices over time showed significantly reduced mortality over the same time. The PRS may be a useful aggregate quality index for HD facilities. It may catalyze an enhanced culture of quality within or across facilities. However, this PRS should be considered to be only the initial version since development and perfection of an aggregate HD quality index will be an iterative process. Further refinements are ongoing to improve the PRS, and to address regional variations in the PRS/mortality relationship.

Acknowledgements. The authors wish to thank the other members of the Canadian Nephrology CQI Advisory Committee: Brendan Barrett, Keevin Bernstein, Kailash Jindal, Adeera Levin, Peter Magner, Garth Mortis, George Pylypchuk and Murray Vasilesky. Amgen Canada, Mississauga, Ontario, Canada, and Amgen, Inc., Thousand Oaks, CA, were the sources of support, and Kirin provided unrestricted funding for this initiative.

Conflict of interest statement. Mahesh Krishnan, MD, is an employee of Amgen, Inc., which provides unrestricted funding for the DOPPS. No other authors have any disclosures to report.

References

1. Wolfe RA, Hulbert-Shearon TE, Ashby VB *et al*. Improvements in dialysis patient mortality are associated with improvements in urea reduction ratio and hematocrit, 1999–2002. *Am J Kidney Dis* 2005; 45: 127–135
2. Petra E, Varughese P, Epifania L *et al*. Use of quality index tracking to drive improvement in clinical outcomes. *Nephrol News Issues* 2006; 20: 67–71, 83
3. Benner D, Hollister D, McAlliser CJ *et al*. The DaVita Quality Index: a measure of clinical performance. *Dial Transplant* 2003; 32: 269–272
4. Young EW, Goodkin DA, Mapes DL *et al*. The Dialysis Outcomes and Practice Patterns Study (DOPPS): an international hemodialysis study. *Kidney Int* 2000; 74(Suppl): S74–S81
5. Goodkin DA, Mapes DL, Held PJ. The Dialysis Outcomes and Practice Patterns Study (DOPPS): how can we improve the care of hemodialysis patients? *Semin Dial* 2001; 14: 157–159
6. Zhang Y, Thamer M, Stefanik K *et al*. Epoetin requirements predict mortality in hemodialysis patients. *Am J Kidney Dis* 2004; 44: 866–876
7. Lowrie EG, Lew NL. Commonly measured laboratory variables in hemodialysis patients: relationships among them and to death risk. *Semin Nephrol* 1992; 12: 276–283
8. Rocco MV, Frankenfield DL, Hopson SD *et al*. Relationship between clinical performance measures and outcomes among patients receiving long-term hemodialysis. *Ann Intern Med* 2006; 145: 512–519
9. Pisoni RL, Bragg-Gresham JL, Young EW *et al*. Anemia management outcomes from 12 countries in the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Am J Kidney Dis* 2004; 44: 94–111
10. Young EW, Albert JM, Satayathum S *et al*. Predictors and consequences of altered mineral metabolism: the Dialysis Outcomes and Practice Patterns Study. *Kidney Int* 2005; 67: 1179–1187
11. Port FK, Pisoni RL, Bragg-Gresham JL *et al*. DOPPS estimates of patient life years attributable to modifiable hemodialysis treatment practices in the United States. *Blood Purif* 2004; 22: 175–180

Received for publication: 2.8.07
Accepted in revised form: 13.3.08