Author's response to reviews

Title: Overview of the Canadian Paediatric End-Stage Renal Disease Database

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Author's response to reviews: see over
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Dear Editor:

We thank you for allowing us to revise and re-submit our article. We submit a point by point response to reviewer’s comments:

Reviewer's report
Title: Performing Clinical Research in Pediatric Nephrology Using Canadian Registry and Administrative Health Datasets
Version: 2 Date: 14 April 2010
Reviewer: Philip Clayton

Reviewer's report:
In this paper the authors describe the creation of the "Canadian Pediatric End-Stage Renal Disease Database", created by linking the Canadian Organ Replacement Register (CORR) and Canadian Institute for Health Information Discharge Abstract Database (CIHI DAD) databases. Although linking 2 databases in this manner is not novel, the resultant database provides vast amounts of information for the study of pediatric RRT outcomes and it is hence likely that this new database will be the source of much research.

No results are presented; rather, this is a methodology paper simply describing the creation of the database. Presumably the idea is that future studies arising from this database can refer to the current paper for details of the database. Therefore this publication is important; however more details are required.

Major compulsory revisions:
1. Insufficient information is given on the linkage process. The authors describe the use of deterministic linkage using personal health information numbers, but do not define deterministic linkage and do not give any information about these numbers, eg is there a check digit? Furthermore, no details are given regarding the success of linkage - what % of patients could be matched? What kind of double checks were performed to ensure that the linkage was accurate (ie in case the personal health information number was entered incorrectly in the CORR database)?

Authors’ Response: We agree that it was important to include additional details of the linkage process. In the revised manuscript, we include a definition of deterministic linkage as performed in this study and more information about personal health information numbers and how they are entered into registry and hospitalization data. Further details are also given on the success of the linkage, as suggested. Sections of the manuscript addressing these concerns are below:

“Each patient identified in the registry was linked to their relevant hospital admissions in CIHI DAD using deterministic linkage methods. Deterministic linkage is accomplished by comparing identifying data fields data from two data sets leading to a judgment on whether two records refer to the same patient. The data element used in the linkage
algorithm for creation of this database consisted of only personal health card number and an exact match of health card number between two datasets was required to match a CORR registrant to corresponding hospitalization records in CIHI DAD.[28] Personal health information numbers are assigned by provincial health authorities and edit checks are performed during CORR data entry process. Personal health card numbers recorded in CORR are validated for length and alpha numeric characters and a check sum is computed for each health card number to detect accidental errors that may occur during data entry. CIHI DAD data has similar checking mechanisms to ensure the accuracy of health card numbers.”

RESULTS

There were 1365 incident end-stage renal disease patients age \( \leq \) 21 years (excluding province of Quebec) identified in the registry for the interval between 1992 and 2007, and 1200 (88%) health card numbers were available for linkage. Among these, 1011 (74.1%) were linked to CIHI DAD for at least one hospitalization episode. There were 9908 hospitalization records for the period 1994-2007 for matched patients (1992-1993 data was unavailable for linkage).

2. No numbers are given. To understand the relevance of this new database we need to know numbers such as the total population, the # of patients included in the registry, the # of patients who were able to be matched and so on. It would also be helpful to know, for example, the total number of hospitalisations included in the database, to get a feel for the scope of the new database.

Authors’ response: We agree that these pieces of information are important, and have included the requested data in the Results section of the revised manuscript. The relevant section is appended here.

RESULTS

There were 1365 incident end-stage renal disease patients age \( \leq \) 21 years (excluding province of Quebec) identified in the registry for the interval between 1992 and 2007, and 1200 (88%) health card numbers were available for linkage. Among these, 1011 (74.1%) were linked to CIHI DAD for at least one hospitalization episode. There were 9908 hospitalization records for the period 1994-2007 for matched patients (1992-1993 data was unavailable for linkage).

3. The socioeconomic and geographic data is based on postal code, but the authors don’t describe how the postal code is recorded in CORR. Is it only recorded on entry, or is it updated when patients move? If the latter, does the new database include socioeconomic and geographic data at each time point? Similarly, does the postal code conversion file (PCCF) document changes in socioeconomic variables over time, and have these been taken into account?
Authors’ response: Postal codes are only recorded at entry in the registry. There is potential to update postal codes and record moves in the future. The socioeconomic and geographic data therefore describes only one time point, at start of renal replacement. Postal code conversion file corresponds to latest Canadian census (2006). Postal codes and socioeconomic information changes with time and is updated with each version of the postal code conversion file. The relevant text in the manuscript is appended below.

“In terms of residence location, the postal codes are recorded on entry into CORR and we cannot capture residence moves presently.”

“PCCF changes with each census and socioeconomic variables are updated with time. The latest available PCCF was from 2006.”

Minor essential revisions:
4. The new database appears to have been named the "Canadian Pediatric End-Stage Renal Disease Database", yet this name doesn't appear in the title or abstract. If this is indeed the name of the database, it should definitely be in the abstract and ideally would also be in the title.

Authors’ response: Title amended to “Overview of the Canadian Paediatric End-Stage Renal Disease Database” and added name of database to abstract.

5. The authors should explain why they only included pediatric patients in this database; from what is presented, there doesn’t seem to be any reason to exclude adults other than logistics.

Authors’ response: We only included pediatric and young adult patients as the focus of investigations for the Pediatric Renal Outcomes Canada Group is pediatric age onset ESRD. This database can be replicated for adult ESRD patients. We do have data for up to age 21 in the present dataset. Relevant text in manuscript is appended here.

At this stage, we have included data only for incident paediatric or young adult patients with ESRD (age ≤ 21) because this population is the focus for our research group; however, the linkage process could be easily replicated in the future for incident ESRD patients who are older than 21 years of age.

6. The figure does not include the PCCF which is effectively a 3rd data source.

Authors’ response: Figure changed to include Postal Code Conversion File

7. Introduction, second paragraph - ANZDATA is the "Australia and New Zealand Dialysis and Transplant Registry" (nb 2 "and"s).

Authors’ response: Typo corrected.
8. In the final sentence of the 6th paragraph of the discussion, "... organ failure registry data - limitation..." should be changed to "... organ failure registry data - a limitation..."

Authors’ response: Typo corrected.

Discretionary revisions:
9. Presumably if patients are hospitalised in other countries (eg the United States) these hospitalisations will not be captured in the new database. This should be mentioned as a limitation of the new database, and ideally the manuscript would include a measure of the likelihood of this occurring.

Authors’ response: We cannot capture out-of-country hospitalizations and likelihood of this is minimal within our universal health care system. Relevant text in manuscript appended here.

“We are also unable to capture hospitalizations in other countries if patients travel abroad, although the likelihood of out-country hospitalizations occurring is negligible in this population.”

10. Such a linkage study provides an opportunity to audit the data in CORR. Did the authors take this opportunity and if so what did they find?

Authors’ response: Yes, we did audit CORR data for outcome death. The results of the audit are described as below in results section of the manuscript.

We also performed an audit of death dates recorded in CORR using available in-hospital death dates. Of all deaths recorded in the database, 25% were in-hospital deaths, and were found in a hospitalization record. Among the in-hospital deaths, 95% of these were also found in CORR data with identical death dates for all except one date.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I am employed by the Australia and New Zealand Dialysis and Transplant Registry, which undertakes similar work and may seek to collaborate with the authors in the future

Authors’ Response: We thank the reviewer for these very helpful comments and look forward to future collaboration.
This paper describes an excellent initiative in the development of a comprehensive database of children with end stage renal failure linking with administrative health data which will allow a significant improvement in outcome data.

Suggested discretionary revisions:
1) In the introduction several registries are mentioned but there could be inclusion of the European ESRF registry eg ref

Authors’ Response: References added and manuscript amended as suggested.

2) In the Methods section page 5 it is stated that the data is not “rigorously” validated. Can the authors report what validation is undertaken?

Authors’ Response: A data quality study on the Canadian Organ Replacement Register was published in July 2009. This study provided important information about the accuracy and coverage of data in CORR. The data quality study involved a chart review for a sample of patient charts, a survey of documentation and coding practices at renal dialysis clinics and an assessment of the participation rate in CORR. We included the results of this data quality study in the manuscript as follows:

The registry data have been used extensively in multiple clinical studies in patients with kidney failure.[3, 20-26] A data quality study on the Canadian Organ Replacement Register was published in July 2009.[27] This study involved a chart review for a sample of 1351 patient charts to assess documentation and coding practices at dialysis clinics, and the participation rate in CORR. In addition, CORR data were compared with data available in the national hospitalization database Canadian Institute for Health Information Discharge Abstract Database (CIHI DAD). It was determined that CORR captures 98.5% of renal transplants performed in Canada. Patient demographics were found to be coded with high reliability in CORR. In contrast, co-morbidities were recorded in CORR with low to moderate sensitivity, indicating a tendency to under-report co-morbidities to CORR. Nevertheless, co-morbidities were recorded with high specificity. The agreement rate between CORR data and chart review data on the
primary renal disease code was 59%, indicating that primary renal disease could be more accurately reported to CORR.

3) In the discussion page 10 it is stated that the “use of the registry and administrative data will limit the ability to collect key clinical variable such as BP GFR and proteinuria”. This is a great shame as understanding the predisposing factors to long term complications is clearly important. What are the issues preventing this data collection?

Authors’ Response: Under the current registry data structure, we do not have clinical variables for GFR and proteinuria. We acknowledge this limitation in the manuscript, as shown below.

“The use of registry and administrative data limits our ability to collect key clinical variables such as glomerular filtration rate and proteinuria which may influence patient and renal allograft outcomes. CORR data collection forms do not include these clinical variables; however, there is potential in the future to link to laboratory databases to obtain this information in certain jurisdictions.”

4) In children growth is major issue in CRF-will data on this be collected?

Authors’ response: Height and weight at start of renal replacement is collected, but there is no longitudinal information on these in the registry. The following sentence was added to the manuscript.

“Height and weight at time of initiation of renal replacement is also recorded in the registry.”

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests: I declare that I have no competing interests