Author’s response to reviews

Title: The management of diabetes in Indigenous Australians in the primary care setting

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Author’s response to reviews:

Did the practitioners include consecutive patients on the same day, the same week or month? How was a consecutive or random inclusion ensured?

Practitioners were requested to recruit consecutive patients presenting to their practice, both in the letter to all GP's requesting expression of interest, and subsequently in the invitation and registration of investigators, project pack instructions, and initiation phone calls. The importance of consecutive recruitment was underlined at all opportunities, although consecutive or random inclusion was not audited in any way. We do not suspect bias in the recruitment of patients as the distribution of patient characteristics are identical to that described in other (smaller) Australian surveys. This data has been previously published and is referenced in the manuscript.

In Australia, approximately 10,000 patients present to their GP every day. Therefore we anticipate recruitment of 10-15 patients took a week or less, but certainly not one day. The study was conducted over a three-month period, during which time GP investigators were requested to conduct this survey.

Is there an indicator that the proportion of indigenous people is the average for Australian primary care?

Yes, the proportion of indigenous patients was similar to that in Australian arm of the DEMAND study including patients with type 2 diabetes and in the Ausdiab study. This data has now been included in the discussion.

Was the study monitored and who were the monitors (CRO, Servier)?

As a cross-sectional audit, the NEFRON study did not have any formal monitoring committee. The Royal Australian College of General Practitioners (RACGP) National Research and Evaluation Ethics Committee approved the study and written informed consent was obtained from all participating patients. Data collection and analysis were managed externally by Quintiles SRS and Statistical Revelations, Melbourne.
Please be more specific on the lab tests used in the methods section. Is there something like a mean age of data, were lab tests confirmed / recorded twice and is there an apparent difference between the quality of lab test between both cohorts?

This data provided in the CRF by the investigators represents the most recent data available for each patient, and upon which it is anticipated that they make their assessment and clinical decisions. We do not know the age of results. However, investigators were specifically requested to record values from blood tests done at one or more routine examination within the last 6-months. If no recent routine values are recorded for any field, practitioners were specifically asked to repeat the tests.

Lab tests were not conformed or recorded twice. As we have examined the results from the Indigenous and non-Indigenous patients presenting to the same practitioner there is no bias or difference between the quality of lab test between cohorts.

No attempt was made to standardise results or centralise testing. These are the results that have been provided by the general practitioners themselves. Consequently, they have many inaccuracies but reflect those encountered in normal practice. This reflects the pragmatic approach taken by this study to generate a picture of patients with type 2 diabetes from the GP’s perspective. This lack of standardisation with respect to study endpoints is acknowledged in the methods and discussion sections and has been detailed in previous reports form the NEFRON study.

Please state whether MAU was measured 3x (which would be appropriate but is not feasible in cross sectional studies), how this may impact on the true prevalence and the relation to the higher number of smokers in the indigenous cohort.

The NEFRON study was limited by restricting classification of the microalbuminuria (MAU) to the most recent ACR for any individual patient. Since there is known to be significant day-to-day variability in albumin excretion, ideally, at least two of three collections in a 3- to 6-month period should show elevated levels before a patient is classified as having an abnormal albumin excretion. Nevertheless, the NEFRON data are consistent with findings from the AusDiab study, which employed three collections and found that 34% of individuals with diabetes had an elevated UAE(11). This acknowledgement has been added to the discussion. We are not clear how this may impact on the prevalence and the relation to the higher number of smokers in the indigenous cohort.

It would be certainly necessary not only to report p-values but also the number of patients in each subgroup (for example age subgroup below 40 ..., figure 2 and others) and the confidence interval for the prevalence rates reported.
Confidence intervals have been added to the figures, which take into account subgroup size

Glycemic control: Please provide all variables that have been adjusted for and the results of the multiple regression analysis.

The difference in glycaemic control between Indigenous and non-Indigenous patients persisted after adjusting for age, gender and the duration of diabetes, variables that were significantly different between indigenous and non-Indigenous patients (see revised methods section). The frequency use of oral antidiabetic agents and insulin was similar in both indigenous and non-Indigenous patients and was not adjusted for. A multivariate logistic model of the predictors of impaired glycaemic control in the NEFRON cohort was not initially built as part of this study. However, an adjusted Odds ratio showing the risk associated with indigenous ethnicity is now provided.

Blood pressure control: Analyses should be adjusted for differences in baseline characteristics. Younger patients usually have better blood pressure control rates. Even in case of no apparent difference a multiple regression analysis would be necessary.

This is an important point. This analysis has now been added and an adjusted Odds ratio showing the lack of risk associated with indigenous ethnicity is now provided.

Lipids: Please provide a more fundamental analysis of these values considering baseline differences between the two cohorts.

This analysis has now been added and an adjusted Odds ratio showing the independent risk associated with GP-identified indigenous ethnicity is now provided.

The same is true for the micro- and macrovascular analyses.

This analysis has now been added and an adjusted Odds ratio showing the independent risk associated with GP-identified indigenous ethnicity is now provided.

Reviewer Two

The term ‘race’ should not be used in my opinion. This implies that the authors view Indigenous Australians as a biologically (genetically?) distinct group, with metabolic abnormalities explained on this basis. This is illustrated in the Abstract where it reads ‘Aboriginal race is a powerful risk factor for micro and macrovascular disease’. It would be more appropriate to use the concept of ethnicity as this acknowledges social and cultural distinctions between groups.

We agree that ‘race’ is a difficult term. We have now removed it from the text.
replacing it with 'ethnicity'.

Ethnicity should normally be self-assigned. How did the practitioners judge whether individuals were indigenous or not? What does indigenous mean? Were their judgments reliable?

The NEFRON study focuses on the practitioner's management of Australian patients with type 2 diabetes. We agree that ethnicity should normally be self-assigned. However, from the point of view of assigning risk and determining diabetes management, we believe that the GP's opinion is also relevant. We recognize that such assignments may not be reliable, indeed, may be completely inadequate. However, data that the GP does not have cannot influence their management. This limitation is acknowledged in the revised discussion.

In the Abstract, where it reads 'Aboriginal race is a powerful risk factor for micro and macrovascular disease', this is of course completely unjustified. Maybe poverty or lack of education are the powerful risk factors for vascular disease. Based on the present data, we just don't know what the risk factors associated with Indigenous ethnicity are - because they have not been measured.

We believe that from the GP's perspective, Aboriginal ethnicity is a powerful risk factor for microvascular and macrovascular disease, which practitioners should use to identify candidates for intensive multifactorial intervention. We acknowledge it may also be a surrogate for other risk factors including poverty, lack of education and other factors associated with socio-economic disadvantage which are strongly linked to adverse health outcomes, independent to ethnicity. However, Indigenous Australian's carry a much greater burden. As seen in other minority populations worldwide(16), socio-economic disadvantage is strongly correlated with the higher prevalence of chronic disease seen in Aboriginal peoples (17; 18). Major disparities in income, housing and education certainly underlie many of the ethnic differences in diabetes care(11). However, many GPs don't have this data, nor is it easily or sensitively obtained in the context of medial care. The clear link between ethnicity (and all that it entails) and risk is a powerful tool to improve the management of diabetes in Australia.

A limitation is that the study adopts a clinical medical perspective and neglects the socio-economic and health system influences that could account for the findings described. The health system determinants should also be discussed. Does the Australian system offer universal access and if so why are outcomes worse for some groups unlike the situation in the UK? Does the Australian system offer universal access and if so why are outcomes worse for some groups unlike the situation in the UK? The lack of data on income, education and other socioeconomic determinants is an obvious limitation.

The NEFRON study was designed to examine factors that influence the management of diabetes within the context of GP-patient encounter. It was not designed to look at the determinants of health outcomes in Indigenous
Australians, but specifically focuses on this one aspect. As such it neglects the pivotal socio-economic educational, and health system influences that contribute to high rates of diabetes and its complications in Indigenous Australians. This deficiency is acknowledged in the discussion. There is little doubt that income, education and other socioeconomic determinants significantly contribute to the ethnic disparity in the delivery and standard of diabetes care. However, it does not explain why perceived ethnicity still does not influence the practitioner’s management of patients with diabetes. The aim of the national health care funding system is to give universal access to health care, including subsidies for prescribed medicines and free or subsidised treatment by practitioners. The health system should be identical for patients attending the same practitioner, and resources are equally available (hence the design of this subgroup analysis). But clearly there is unmet need, in the context of heightened risk for complications. We can’t comment on these findings as they relate to the practice of diabetes care in the UK.

The Discussion would be improved by referring to some of the literature on race, culture and ethnicity, in particular, the role of socio-economic factors in explaining ethnic inequalities in health.

This study is not in a position to comment on the role of economic determinants of health outcomes, as we did not collect this data. Nonetheless, the discussion has been expanded to include more of the literature dealing with the role of socio-economic factors in explaining ethnic inequalities in diabetes care and the AMA position statement on the issue.

Minor comments

Abstract: avoid vague terms like 'smoking was also common'
This sentence has been amended

'Same (younger) age' is not clear, non-I patients were older
This sentence has been amended

The meaning of the term 'incident driven' is unclear.
We have removed this term

Table 1. Give confidence intervals. Give exact p values rather than asterisks. It is not clear what role the logistic models had in the interpretation of results, and whether P values should be adjusted, for example for age differences.
Univariate and multivariate (adjusted) significance has now been added to the table.
Frequency of findings are now expressed as a percentage with a 95% CI

Figure 2. An overall test for difference between groups would be better than a significance test at each different duration of diabetes.
Error bars have been added to assist in interpretation of this figure.

Figure 3. The data would be better presented as a Table with confidence intervals for the age-specific rates.

We believe that a graphical representation of the data provides a better impression of the differences in diabetic complications between Indigenous and non-Indigenous patients. Error bars (confidence intervals) have been added to assist in the interpretation of this data.