Reviewer's report

Title: Design of a prospective cohort study to assess ethnic inequalities in patient safety in hospital care using mixed methods.

Version: 4 Date: 21 June 2012

Reviewer: Abdulrahman El-Sayed

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This study seeks to understand ethnic differences in in-hospital adverse events as well as their multilevel predictors using data from four hospital sites in the Netherlands. Overall, the protocol has several strengths, including its prospective design, it’s rigorous chart review process, and it’s use of four different sights in three cities in the Netherlands. However, the protocol does have some deficiencies and areas for improvement, which I discuss below.

Major Compulsory Revisions:

1. Excluding non-Western non-Dutch to increase SES disparities between the ethnic and non-ethnic samples will increase confounding by SES. The protocol seems unclear, in this regard, about what the variable of interest is: is it ethnicity or SES or a combination of the two, such as ethnic marginalization—or something else?

2. Similarly, the protocol is conflating “immigrant” with “ethnic”—a large proportion of ethnic minorities may be Dutch-born, although they remain ethnic minorities. In this way, the findings of the study will not generalize to the ‘ethnic’ population, simply the ethnic immigrant population, and increasingly small portion of ethnic minorities in Western Europe.

3. Giving charge nurses the responsibility of recruitment in each ward may be less systematic than would be ideal. Perhaps it would be good to systematize inclusion/exclusion protocols across wards/hospitals further? I am particularly concerned with nurses’ capacity to exclude based on disease severity and the potential for selection.

4. It is plausible that the distribution of admissions by disease may differ by ethnicity—what impact could restricting your study to a few specific wards have on the outcomes? Could this impose a selection bias?

5. The investigators might consider a matching protocol to increase baseline exchangeability between groups.

6. Ethnic attribution is highly inappropriate: “We will initially estimate a patients’ ethnic background from the surname, exterior characteristics, and presumptions of a senior nurse.” Self-report would be more appropriate.

7. How are the researchers controlling for baseline health status prior to
admission? This would seem to be an important confounder of the relationships of interest.

Minor essential revisions:

8. The abstract does not adequately describe the qualitative aspects of the study.

9. Using country of birth may not be a strong proxy for ethnic origin, rather a self-reported ethnicity measure may be more appropriate.

10. Questionnaires should be translated and back-translated in each of the languages of the main ethnic minority groups to be included in the study. Moreover, bilingual study personnel should be available in each language.

11. An objective language proficiency test would be better than the subjective assessment currently in place.

12. “Subjective health literacy score” should be further explained.

13. With respect to the statistical analysis, the authors may consider pursuing structural equation modeling, which may be better suited than simple multilevel regression approaches to testing their mediation hypotheses across comparison groups in a multilevel framework.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

There are no competing interests to declare.