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: 3 July 2012

Reviewer: Jennifer Hollowell

Reviewer’s report:

This paper describes the design for a study to quantify and explore possible differences in adverse patient safety events between native Dutch and non-Western patients admitted to Dutch hospitals.

The study uses a mixed methods design that includes a hospital based prospective cohort study to capture data on patient characteristics and adverse events, followed by a qualitative interview survey to explore possible mechanisms in a sample of admissions.

DESIGN OF THE PROSPECTIVE COHORT STUDY

Data collection started in December 2010 so the study described in this protocol is currently in progress.

1. The protocol describes many aspects of the study methods in detail but some aspects of the study are not dealt with in sufficient detail.

1.1 There is no indication of whether any attempt is being made to measure and evaluate non-response. Given that the study is/will be recruiting patients who may have limited fluency and possibly literacy) in the Dutch language it would have been helpful to see a discussion of the effect this might have on participation and response rates.

1.2 The identification of adverse event ‘triggers’ appears to be based on objective criteria but it is assumed that the physician assessment of causation, preventability, etc is not blinded to the patient group. It would be helpful for the authors to discuss the potential risk of bias that this might introduce. The authors discuss ‘hindsight bias’ but do not appear to consider that forms of assessment bias might affect the two study groups differently.

1.3 It is very unclear whether (and/or how) the authors intend to address or control for possible differences in casemix or other clinical characteristics between the two study groups.

2 The authors need to justify the sample size.

ANALYSIS PLAN

Given that the study is already in progress, the main value in publishing the protocol is to provide details of the planned analyses. This is particularly
important in a study of this kind where a substantial number of variables relating to patient characteristics and outcomes are being collected. There would appear to be a serious risk of spurious associations being found as a result of multiple testing.

3.1 The authors therefore need to describe their planned analyses in considerably greater detail. Inevitably some analyses will be exploratory but the authors need to be explicit about key pre-specified analyses.

3.2 For the ‘first research question’ it is unclear whether they have a primary question or outcome. If it is assessing the difference in the overall AE incidence rate, it would be useful to state this. If their aim is more descriptive and exploratory then this also needs to be stated. It appears that they plan to describe the characteristics of AEs but it is unclear whether they plan to test for specific differences between AEs in the two groups. They need to provide further details of their proposed analysis strategy including definitions of the variables to be analysed, e.g. how they will be categorised.

3.3 For the ‘second research question’, the authors list the explanatory variables that they propose to explore but these are described only in general terms. The main analysis variables need to be defined in detail and the authors should explicitly state which variables they propose to test. For example, how will the various socio-economic variables be categorised? Do they propose to analyse and test all of the socioeconomic variables?

3.4 The authors need to be more explicit about how they intend to control for confounding. What do they consider potential confounders?

3.5 At their discretion, the authors may also wish to outline exploratory analyses that they propose to conduct and any issues that might arise (for example a high non-response rate or poor participation by a particular centre) that might lead them to modify their analysis plan or conduct additional sensitivity analyses.

STRENGTHS AND LIMITATIONS

4. The authors need to provide a fuller discussion of the potential weaknesses of the study and how they consider that they will be able to address these. In particular, they need to discuss the points noted above (non-response, potential assessment bias, and interpretation of multiple statistical tests).

REPORTING GUIDELINES

5. It is not necessary for a protocol to adhere to specific reporting guidelines but the STROBE reporting guidelines for cohort studies will be applicable to the study report in due course. I would suggest that the authors review the STROBE checklist and consider whether it is possible for them to cover items in the methods checklist in this protocol. If the authors intend (and are able) to report the cohort study according the STROBE guidelines it might be appropriate to state this in the protocol.

MAJOR COMPULSORY REVISIONS
The authors need to provide a much more detailed analysis plan as outlined above (3.1-3.4) and to address comments relating to:

• Measurement and potential impact of non-response (1.1)
• Potential assessment bias (1.2)
• Sample size justification (2)
• Potential sources of confounding and how they propose to address confounding in the analysis (3.4 and 1.3)
• Limitations of the study (4)

DISCRETIONARY REVISIONS

See comments 3.5 and 5 above.

**Level of interest:** An article of limited interest

**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 interest