Reviewer's report

Title: The SAIL Databank: building a national architecture for e-health research and evaluation

Version: 1 Date: 31 March 2009

Reviewer: Fortunato Castillo

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Major Compulsory Revisions

1. The authors chosen format for publication seems to be inappropriate for the message that is to be conveyed. The current format draws a somewhat artificial distinction between Methods and Results.

The Study Protocol format (outlined at: http://www.biomedcentral.com/bmchealthservres/ifora/?txt_jou_id=2037&txt_mst_id=2011) would be better suited with its Method/Design section.

2. Page 6, Paragraph 1, Line 4. The independent internal audit is an extremely important element of this article and there needs to be much more detail here. The following information needs to be provided:
   - Who carried out the audit (what was the name of the international company?)
   - What was the controls audit framework that was used?
   - Would it be possible to provide the full audit report as an appendix to this manuscript?

3. The authors outline a fairly complex journey for the SAIL dataset that begins at the Data Provider Organisation, through Health Solutions Wales and the Health Information Research Unit and out to researchers. The workflow needs to be represented more clearly. Although it is described within the text this should also be illustrated in diagrammatic form.

4. Although the authors describe their record linkage technique that enables related person-based records to be linked both within and between datasets. They do not provide any evidence that they have actually linked any of the 500 million person-related records. If this has been achieved then we need to see details. Please provide the figure for the total number of people whose records have been collected in SAIL and some indication of the current success that has been achieved in linking across all the datasets that are listed in Table 1.

5. Page 6, Paragraph 1, Line 9. The authors make reference to wide consultation with regulatory and government agencies but provide no evidence of this. This should be provided, possibly in the form of a table to indicate the bodies with whom the authors have consulted, the nature of this consultation and key points that have emerged. Relevant correspondence with these agencies should be included in the appendix to this article.

6. Page 8, Paragraph 2, line 3. How is the process of due diligence supported by
HIRU? Please explain.

7. The Information Governance Review Panel is referred to however its Terms of Reference are not provided. How does the IGRP assess each proposal for IG compliance, SOPs and data management policies? How is disclosure risk assessed? The Terms of Reference need to be provided along with the Standard Operating Procedures and Data Management Policies.

8. Page 12, Par 2, Line 4. What does the phrase “do not have facilities to allow data to be transferred out” actually mean? Please re-phrase.

9. Page 12, Paragraph 2, Line 6. Please define what is meant by a “secure terminal”.


11. Page 12, Paragraph 2, Line 7. How do the HIRU team scrutinise the statistical outputs? Do they make use of any tools or guidelines or is this purely subjective human assessment?

12. Page 12, Paragraph 2, Line 8. Please provide the “Access Agreement” as an appendix to the article.

13. Page 12, Paragraph 3, Line 6. The assessment areas are referred to by letters a – e however these seem somehow to relate to 1 – 7 in the methods section this is confusing and needs to be corrected.

14. Page 12, Paragraph 3, Line 9. The data haven is not described above, as stated. (see point 9).

15. Page 13, Paragraph 1, Line 6. The backup schedule may be clear to the authors, however this should be stated in the text of this article.

Minor Essential Revisions

16. The authors consistently refer to the NHS Information Governance Framework as “Information Governance”. This is ambiguous and should be corrected.

Minor Essential Revisions

None

Discretionary Revisions

None

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 interests