Author's response to reviews

Title: The South London and Maudsley NHS Foundation Trust Biomedical Research Centre (SLAM BRC) Case Register: development and descriptive data

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Response to reviewers

We are very grateful for the helpful and constructive comments of both reviewers. We note that only one reviewer asked for amendments and we are pleased to respond to their suggestions as follows:

Major compulsory revision

1. *The paper goes to some lengths to explain how patients' identities are hidden in the text reports. Are the identities of clinicians (including referrers) similarly protected? If someone wanted to do a study comparing the outcomes of patients treated by different psychiatrists, would the relevant data be extractable? That is, could one search on a provider's name?* There is no anonymisation of health service staff in this register – this issue was considered in both the internal (Trust Executive) and external (research ethics committee) review. Our advice has been that there is no requirement in UK law to anonymise staff information in clinical records. There would, however, be a ‘duty of care’ by the Trust to ensure that data relating to its staff were not used in an unauthorised or unprincipled manner. This is partly covered by the Committees set up to consider and approve Trust audit projects and partly by the Oversight Committee responsible for the Case Register. The suggestions raised by the reviewer would be viewed as audit rather than research. We have clarified in the text that the Case Register can be used for Trust audit projects but that these would require specific approval by the appropriate body (i.e. one of the Trust audit committees which review all proposed Trust audit projects). It would be highly likely that both the Audit Committee and Oversight Committee would consider the project suggested by the reviewer as an unprincipled use of the data if individual clinicians were being compared without assurance of anonymity or if searches were carried out on an individual clinician’s name (an action which would be identified as having occurred in the log which records all Case Register searches, as described in the paper). We have added text under the ‘procedural measures’ section of the Methods which we hope clarifies this issue.

Minor essential revisions

1. *Page 6 makes reference to "the principle of 'consent or anonymise' ". I have never heard of that principle and I suspect many readers also. Is there a relevant reference? My understanding is that consent for research includes the freedom to withdraw for any reason without notice. How would identifiable information be handled if consent were withdrawn?* We have added more text on this issue and a reference. What is referred to is UK case law (the ‘Source Informatics ruling’) interpreting the European Data Directive. We have mentioned that our system allows for ‘opting out’ (i.e. complying with a request from a service user to remove data on their record from the register). The way in which this works is by masking the respective source case records to the search engine so that they would not appear in
any searches (since we cannot obviously delete a source clinical record). We have added text on the respective page to clarify this.

2. On pages 9 and 22, it is the Health of the Nation Outcome Scales, not Scale. This has been corrected.

3. Page 13 – 14, Procedural issues. Is approval from the committee that oversees the use of the register additional to the institutional research approval that all research must obtain? Does this mean that a study that wanted to use the register would have to seek two approvals? What is the composition of the register committee, and is there a cost to using the register? We have added text to describe the membership and role of the Oversight Committee as well as the (single) approval system. The use of the Case Register for secondary analysis of anonymous data has received the necessary internal and external approvals and one of the roles of the Oversight Committee is to ensure that projects do not violate existing approvals (for example by compromising anonymity). There is no cost to use the register.

4. Page 14-15. The case register has the capacity for patients to opt out, but that has never happened. This is surprising given that many psychiatric patients are very sensitive about their personal information being held on a mental health database. That no-one has sought to opt out may have to do with the possibility not being well advertised, and the process being awkward. The authors should comment on this. We have removed the statement that opting out has not happened. At the time of writing, we have still received no requests yet for this, despite a programme of dissemination to ensure that service users are informed about the use of anonymised data on clinical records for research. However, we agree that it will happen eventually and that the statement may risk being out of date. We have added text on the ongoing dissemination process (also referred to in Table 3).

5. The ethnicity classifications in Table 4 appear to confuse country of birth with "ethnicity", which is usually determined by self-assignment. Presumably patients are assigned to only one ethnic group. It is potentially offensive that a patient classified as, for example, Caribbean, is by implication classified as not British. If what is called "Ethnic group" is actually country of birth, this should be made clear. If not, the authors should explain how patients' ethnecities are determined. We have added text to the footnote of Table 4 clarifying the definitions of ethnicity. Self-assigned ethnicity is enquired about and coded in the source records by Trust staff. The codes used in the source records are standard across UK health services. We share the reviewer’s reservations but feel that it would not be valid to alter the names or structure of the categories as these reflect the source data and the coding system used across this and other health services.

6. Page 16, Table 5, diagnoses. What allowance made for comorbidities? These results reflect the primary assigned diagnosis. Multiple diagnoses are allowed in the source records but we feel that a full reflection of comorbidity would be beyond the scope of this paper. We have clarified this in the Results text.

7. Page 20. What is "omics data resources"? We have clarified this term in the text where it occurs.
8. Some non-ASCII characters have crept into reference 9. This has been corrected.

9. The register is promoted as a resource that will support research, but no studies that have used the register are reported. Have there been any? There are now a large number of projects which have been using the register since it was set up in October 2008 but, given the short time period, no other publications to date. We report here the establishment of the case register and will publish research studies separately.

Discretionary revisions

1. Page 9. The PJS "is a comprehensive record of all clinical information . . . " and examples are given. Does the PJS also incorporate imaging information? Imaging information is not incorporated within PJS except in so far as summary findings are written in clinical records. Links with imaging data are an aspiration for future development of this resource. We have added text to clarify this.

2. Page 10 and Figure 2. I think most readers of a psychiatric journal will have little interest and understanding of the technicalities of database design and structure, and this material could be omitted with little loss to the overall story. We are happy to accept Editorial judgement on this matter but would prefer to keep this information as it is integral to a description of the design of the system and will maximise the usefulness of the paper as a reference source for further papers (which may not always be sent to clinical journals).

3. Table 3 makes reference to a "security protocol" but this is not mentioned in the text. We have amended ‘security protocol’ to ‘security model’ for consistency.