Author's response to reviews

Title: THE SAAF STUDY: A Randomised Trial and Implementation Evaluation of the Safeguarding Children Assessment and Analysis Framework (SAAF) compared with management as usual for improving outcomes for children and young people who have experienced maltreatment or who are at risk of maltreatment.

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Author's response to reviews: see over
<table>
<thead>
<tr>
<th>Comment</th>
<th>Original</th>
<th>Revised</th>
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<tbody>
<tr>
<td><strong>Abstract</strong></td>
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<td>1</td>
<td>1st sentence under Methods / design could be simplified grammatically to make it easier for the reader to understand.</td>
<td>The multi-site, cluster randomised trial will assess whether training in, and use of, SAAF improves social work assessments of harm, of future risk and parent’s capacity for change, and results in lower rates of re-abuse. The comparison is management as usual.</td>
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<td>2</td>
<td>3rd sentence under Methods / design – seems like there is a grammar issue particularly whether the “;” is appropriate here.</td>
<td>Inclusion criteria for the study are: Children’s Services Departments (CSDs) in England who were willing to make teams available to be randomised; to make staff available for training and to require all staff, irrespective study arm, to comply with the research team’s data requirements.</td>
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<td>3</td>
<td>The dates of recruitment are not needed in the abstract.</td>
<td>Six CSDs were recruited between January and May 2014.</td>
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<td>4</td>
<td>Seems like there may be a grammar issue in the sentence beginning “The primary outcomes …” The sentence was a bit hard to understand.</td>
<td>The primary outcome is child maltreatment, assessed via administrative records of children being subject to a Child Protection Plan (CPP) for a second or subsequent time (or for the first time following an assessment that did not result in a CPP), as a result of concerns linked to the original assessment, and through re-referrals.</td>
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<td>Same comment for the next sentence.</td>
<td>Secondary outcomes are the quality of assessments and the relationship between SAAF assessment judgements, overall assessments of risk and child protection plans.</td>
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<td>Background</td>
<td>The UK Government is currently implementing a number of the recommendations made in the Munro Report[1]. This includes revised guidance on inter-professional collaboration in child protection [2] and the removal of a requirement for local authorities first to conduct an initial assessment, followed by a core assessment, each within a set number of days (10 and 35 respectively). An important achievement of the Munro Report was to focus attention on the unintended consequences of seeking to improve assessment and decision-making by increasing the burdens of regulation and guidance, the ‘over-scaffolding’ of practice with detailed procedures, and focusing on the collection of information by social workers, rather than its analysis. Structured decision-making (SDM) has been defined as a ‘general term for the carefully organized analysis of problems in order to reach decisions that are focused clearly on achieving fundamental objectives’. SDM draws both on decision theory and risk analyses and, in the field of child protection, has been described as ‘an example of an effort to integrate predictive [actuarial] and contextual assessment strategies’ [3]. So, for example, the Family Strengths and Needs Assessment (FSNA) is a structured approach to assessing (including scoring) child and family functioning in those domains recognised as important in child protection. In 2010, Professor Eileen Munro was commissioned to chair a review of the child protection system in England. As part of a wide-ranging brief, she was charged with generating ideas about how to improve early intervention, enhance trust in frontline social workers and improve transparency and accountability in child protection. A central question for the review panel was ‘what helps professionals make the best judgments they can to protect a vulnerable child?’ [1,p.6]. The final report [1] highlighted the failure of historical attempts to improve assessment and decision making via increased regulation, guidance and procedural requirements, rather than by developing and supporting the analytic and decision-making skills of social workers. It therefore recommended moving away from a culture of prescription and compliance (the ‘status quo’) to one that emphasised the importance of professional judgement. Achieving this necessitates ensuring that staff are equipped with the necessary knowledge and skills to exercise sound judgement, and chapter 6 of the Final Report addresses these issues in detail, noting the importance of the ‘ability to analyse critically the evidence about a child and family’s circumstances and to make well-evidenced decisions and recommendations, including when a child cannot remain living in their family either as a temporary or permanent arrangement; and skills in achieving some objectivity about what is happening in a child’s life and within their family, and assessing change over time’ (p.96).</td>
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<td>1</td>
<td><strong>The 1st paragraph would benefit from a clearer discussion of the Munro report, what specific “deficits” from that report are addressed in this study and how. The general idea is there, but the unfamiliar reader would benefit from a bit more description. Could also tie in this first paragraph a bit more clearly with the next one that launches into the idea of shared decision-making.</strong></td>
<td><strong>The UK Government is currently implementing a number of the recommendations made in the Munro Report[1]. This includes revised guidance on inter-professional collaboration in child protection [2] and the removal of a requirement for local authorities first to conduct an initial assessment, followed by a core assessment, each within a set number of days (10 and 35 respectively). An important achievement of the Munro Report was to focus attention on the unintended consequences of seeking to improve assessment and decision-making by increasing the burdens of regulation and guidance, the ‘over-scaffolding’ of practice with detailed procedures, and focusing on the collection of information by social workers, rather than its analysis. Structured decision-making (SDM) has been defined as a ‘general term for the carefully organized analysis of problems in order to reach decisions that are focused clearly on achieving fundamental objectives’. SDM draws both on decision theory and risk analyses and, in the field of child protection, has been described as ‘an example of an effort to integrate predictive [actuarial] and contextual assessment strategies’ [3]. So, for example, the Family Strengths and Needs Assessment (FSNA) is a structured approach to assessing (including scoring) child and family functioning in those domains recognised as important in child protection. In 2010, Professor Eileen Munro was commissioned to chair a review of the child protection system in England. As part of a wide-ranging brief, she was charged with generating ideas about how to improve early intervention, enhance trust in frontline social workers and improve transparency and accountability in child protection. A central question for the review panel was ‘what helps professionals make the best judgments they can to protect a vulnerable child?’ [1,p.6]. The final report [1] highlighted the failure of historical attempts to improve assessment and decision making via increased regulation, guidance and procedural requirements, rather than by developing and supporting the analytic and decision-making skills of social workers. It therefore recommended moving away from a culture of prescription and compliance (the ‘status quo’) to one that emphasised the importance of professional judgement. Achieving this necessitates ensuring that staff are equipped with the necessary knowledge and skills to exercise sound judgement, and chapter 6 of the Final Report addresses these issues in detail, noting the importance of the ‘ability to analyse critically the evidence about a child and family’s circumstances and to make well-evidenced decisions and recommendations, including when a child cannot remain living in their family either as a temporary or permanent arrangement; and skills in achieving some objectivity about what is happening in a child’s life and within their family, and assessing change over time’ (p.96).</strong></td>
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<td>2</td>
<td><strong>Grammar issue in sentence beginning “An important achievement....”</strong>.</td>
<td>An important achievement of the Munro Report was to focus attention on the unintended consequences of seeking to improve assessment and decision-making by increasing the burdens of regulation and guidance, the ‘over-scaffolding’ of practice with detailed procedures, and focusing on the collection of information by social workers, rather than its analysis.</td>
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<td>3</td>
<td><strong>Spell out DfE before using abbreviation</strong></td>
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<td>4</td>
<td><strong>Grammar / clarity issue in sentence beginning “Both address....”</strong>.</td>
<td>Both address the three domains of the Assessment Framework [5] (the child’s development needs; family and environmental factors, and parenting capacity) and which comprises the statutory guidance provided to professionals.</td>
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<tr>
<td>Methods</td>
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<tr>
<td><strong>1</strong></td>
<td>Please check grammar of sentences in Inclusion and Exclusion sections</td>
<td>Children’s Services Departments in England who were willing: to make teams available to be randomised to each arm in the trial; to make staff available for training, and to require all staff, irrespective of study arm, to comply with the research team’s data requirements.</td>
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<td>Children’s Services Departments where: there are concerns about performance (e.g. special measures, other Department for Education involvement); where a major organisational restructuring is planned or under way; or where other risk assessment tools are being used, irrespective of whether they are being evaluated e.g. Graded Care Profile, Signs of Safety, or where the Department has received recent training from Child and Family Training (SAAF developers).</td>
<td>Children’s Services Departments were not eligible if one or more of the following pertained: there were concerns about performance (e.g. special measures, other DfE involvement), a major reorganisation was planned, the CSD was already using another risk assessment tool (e.g. Graded Care Profile or Signs of Safety), the CSD had received training in recent years from the providers of the intervention, namely Child and Family Training.</td>
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<td><strong>2</strong></td>
<td>Last sentence under Social Work Teams: consider moving this earlier in the paragraph rather than after the discussion of teams that would not be eligible.</td>
<td>‘Eligible teams within each CSD will be those that – between them - deal with the majority of complex Section 17 and Section 47. Generally, this will exclude teams that are working with looked after children, court........ In CSD-wide teams it is not possible to prevent contamination of either social workers or cases i.e. SAAF-trained social workers would be sharing an office and other resources with those in the control group, and cases assessed in the first instance by a social worker in the experimental group might well end up on the caseload of a social worker in the other control group (and vice versa). Social workers in these teams are eligible, irrespective of experience or whether they are employees or agency staff. Generally, this will exclude teams that are working with looked after children, court....’</td>
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| 3 | Provide information about the time frame in which outcomes will be assessed (e.g. how long after the assessment is administered). | The following new section has been added at the end of the section on Primary and Secondary outcomes, and before section on Intervening Variables.  
**Timeframe**  
Primary outcomes will be assessed at six and 12 months after the completion of an assessment.  
Assessment quality will be assessed once the social worker’s assessment has been signed off by the relevant line manager. The relationship between SAAF assessment judgements, overall assessments and child protection plans will be undertaken when data are available on all assessments included in the trial, together with analyses of the relationship between the three summary judgements and subsequent maltreatment.’ |
| 4 | Describe who will provide the post-training telephone consultancy. | • Limited post-training telephone consultancy to discuss problems and issues that might have emerged.  
• Limited post-training telephone consultancy, delivered by the trainers (Child and Family Training) to discuss problems and issues that might have emerged. (p.13) |
| 5 | For the quality assessments (pages 15-16), provide more description on how they will be assessed and by whom. | The following paragraph has been added after the first paragraph under 1. Quality of assessments undertaken using SAAF:  
‘When 1800 complex assessments have been completed, the Clinical Trials Unit will randomly select 10% of assessments, stratified by study arm and size of CSD. These 180 assessments will then by quality assessed by members of the research team, blind to whether the assessment is from the experimental or control arm of the study. It is not possible to blind the assessors to CSD given the forms used in each department. The researchers will be asked to record any information that might lead them to believe they know the arm from which the assessment was drawn e.g. reference to SAAF.’ |
|  |  | The section under ‘Measures’ (Secondary outcomes) has been rewritten to give some detail on how the scoring will be done. See current page 16.  
• Data relating to the quality of assessments will be recorded using a quality assessment schedule |
developed for this study. This requires the assessor to collect information on 44 items related to assessment quality.

For 30 items the responses are simply ‘yes’ (score 1) or ‘no’ (score 0). For example, item 27 asks ‘Does the assessment make clear the changes required in the child’s care to make the child/ren safe?, and the responses open to the assessor are: ‘Yes, the assessment makes clear the changes required in the child’s care to provide them with adequate parenting’ or ‘No, the assessment fails to make clear the changes required in the child’s care to provide them with adequate parenting’.

For the remaining 14 items there are three possible responses, reflecting the factor being assessed e.g. item 24 asks ‘If included, is there evidence that, in reaching their problem formulation, the author considered other, plausible explanations?’ and the assessor is asked to select from the following three responses, scored respectively 2,1,0: ‘The assessment provides evidence that the social worker considered alternative theories that might explain how the present situation has come about, and has provided reasons why s/he favours the one put forward.’; ‘The assessment provides no evidence that the social worker considered alternative theories that might explain how the present situation has come about, but s/he provides reasons why/evidence for the hypotheses being proposed.’, ‘The assessment provides no evidence that the social worker considered alternative theories that might explain how the present situation has come about, and no reason/evidence for the hypotheses being proposed.’ The maximum possible score for any assessment is 48.

This is not a validated tool, but it is based on factors known to be associated with quality assessments. Whilst SAAF is designed to improve assessment and analysis, the tool is not biased towards the content of SAAF. Researchers will be provided with a user guide, which provides guidance on what is being looked for, and how to score items. For example, in relation to item 24 (above) about problem-formulation, the user guide states: “Research indicates that premature conclusions can lead to mistakes, some of which can be fatal. It is good practice to consider alternate explanations or theories, and to be able to articulate why one has opted for one particular explanation/theory, rather than another.” The schedule will be piloted, the findings discussed, and re-piloted, until a satisfactory rate of inter-rater reliability is achieved. Assessors will receive training in the tool, and will be required to attain a satisfactory reliability rating before assessing SAAF and Control assessments.

- information gathered from social workers on their approach to assessment, information collected and their confidence in the assessment and, where relevant, the proposed child protection plan.

6 Consider combining sections on Primary and Secondary outcomes that appear twice (pages 15-16 and 21-22).

The material on Primary and Secondary outcomes that appeared on pp. 21-22 has been integrated into the text on pages 15-16.

Primary outcomes
The paragraphs under Primary Outcomes on original page 21 have been deleted, retaining only the
references. The following section can be found on pages 14-15 of the resubmitted document.

**Primary outcome**

Differences between the two arms in the proportion of cases resulting in maltreatment or recurrence of maltreatment following the completion of an assessment (section 17 cases) or initial child protection conference (section 47 cases).

**Measures**: using administrative data (CiN data) collected by local authority CSDs we will assess the (re)occurrence of maltreatment, as defined by:

- Number of children who become subject to a second Child Protection Plan (CPP) for a second or subsequent time (or for the first time following a S47 or S17 assessment that did not result in a CPP), as a result of concerns linked to the original assessment;
- Number of reassessments or re-referrals as a result of concerns linked to the original maltreatment/perceived risk of maltreatment;

At a national level, the CiN data include items such as ‘Initial Category of Abuse’ and ‘Latest category of abuse’. In order to determine whether or not the trigger incidents are related i.e. are indicative of a failed plan or inadequate assessment, data are needed that provide information at a more granular level than that typically collected for the National Statistics Office (the annual CiN return). For this purpose we will use the more detailed data gathered by the Children’s Services Departments (information management) and collect data immediately post-assessment from social workers via an electronic questionnaire (the Case Report Form). These data will provide us with information about the concerns of social workers, their confidence in their assessments, their plans and assessments of future risk. They will also ensure that i) we do not miscategorise apparently unconnected events that in fact have a common underlying cause. For example, physical abuse by a parent and sexual abuse by a stranger may be unrelated, but they may also be symptoms of a seriously neglectful environment; ii) we can link children who move between one form of assessment or focus to another e.g. S17 to S47 and monitor associated changes in assessment.

**Secondary outcomes**

The first paragraph under secondary outcomes on page 22 has been incorporated in the revised text on pages 15-16 – see above, point 5

Text on the analyses of the SAAF judgements (p. 22 of previous submission) has now been incorporated into the relevant section under **Secondary Outcomes** (current version p. 17)

2. **Relationships between SAAF assessment judgements (55), overall assessments (3) and child**
**protection plans/interventions.**

In the review that identified SAAF as a promising tool to improve social work safeguarding assessments [4], the authors emphasise the importance of assessing the reliability and validity of the SAAF as a ‘tool’ to improve the classification of risk and the development / availability of evidence-based programmes for those families assessed using SAAF.

We cannot directly address issues of inter-rater reliability within the resource constraints of the current project, but we will investigate:

- the extent to which the structured approach (55 judgements) are linked to the three summative assessments of harm, risk and prospects for intervention; to recorded variations in child protection plans, and to the primary outcome.
- the extent to which the three summary judgements are linked with subsequent maltreatment or its absence.

Data relating to the 55 judgements and 3 summative judgements used in SAAF will be obtained directly from the SAAF forms used by social workers in the experimental arm, and from the Case Report Forms.

| 7 | Reference is made to “section 12”. This is not clear. | Deleted along with other deleted text – see previous point. |
| 8 | There are some details of the methods section that, although important for an IRB, are not essential for readers of the manuscript. In particular this applies to some sections under Data management = Security and confidentiality, as well as Data Monitoring and Auditing. Recommend reviewing these sections and omitting details that are not essential for the reader of the manuscript to understand the trial. | Security  
All data will be managed and stored in compliance with ICH GCP 1996 following trial specific standard operating procedures (SOP) as given in the trial master file, and in accordance with QUB and NI CTU Information Management and Security Policy and QUB / NI CTU Data Protection Policy.  
Case report forms will be completed on-line by social workers, using a unique identifier for both the Social Worker and the Family.  
Baseline questionnaires will be anonymised, scanned and stored securely at the NI CTU, separately from any information that could identify participant social workers. Paper records will be stored in a secure and accessible place and will be maintained in storage for a period of 3 years after completion of the study.  
The method of access to social work assessments will be agreed on a local authority by local authority basis. In all cases access to assessments will be secure, and no identifying details (of the family/child) will be recorded. These assessments will be made available purely for the auditing of their quality and not their content.  
All original paper records will be anonymized, scanned and the resultant pdf files stored securely. All data will be entered. | Section on Auditing and Data monitoring deleted, and section on Data management edited as follows:  
Case report forms will be completed on-line by social workers, using a unique identifier for both the Social Worker and the Family. All data will be stored in a securely and no identifying details of the family/child will be recorded.  
The Department for Education will flag each child whose assessment is used in the trial to facilitate later follow up, should funding be available. These data will remain anonymised (i.e. no child’s name would be used).  
All data will be monitored using central statistical monitoring for consistency, viability and quality.  
Data from the study will only be presented in public once the main results are published in peer reviewed journals according to CONSORT guidelines and disseminated to all the study participants (CSDs) in an accessible format. |
into a database and validated. Queries will be recorded, logged and tracked until resolution in line with the data management SOP.

Electronic data will be stored as csv files and Stata data files (.dta) in the NI CTU or QUB, both of which provide appropriate levels of environmental and physical security on servers that are managed in accordance with an appropriate Systems Management Policy. Confidential information will be registered with the Archivist and Records Manager and data will be stored on a secure server which maintains an audit trail demonstrating system access. A centralised network backup service is used. All data will be stored in accordance with QUB Data Protection Policy.

Confidentiality

Social workers will be given a unique identifier by the NI CTU at randomisation. The NI CTU will also assign a unique identifier to each assessment completed. The social worker will collate a list of these unique study identifiers so that the data can be correlated (anonymously) to the Department’s Management Information which will then be supplied anonymously to the research team by each local authority.

Cases will be identified using the LA’s unique identifier.

The Department for Education will flag each child whose assessment is used in the trial to facilitate later follow up, should funding be
available. These data would remain anonymised (i.e. no child’s name would be used).

For the purpose of recruitment local researchers and the Trial Manager at Queens will store all potentially identifying detail in an on-line password-protected database which will be the only data linking participants to the study ID number.

Electronic outcome data will be stored at the NI CTU in a password protected electronic database in which particular assessments and social workers will be identified only by study specific numbers.

**Data monitoring**

All data will be monitored using central statistical monitoring for consistency, viability and quality. Given the nature of the data required for this study, and the study timeline, an independent Data Monitoring Committee will not be established. Instead, the Trial Management Group (comprising PI, TM and NI CTU) will monitor the quality of the data as part of their monthly meeting, and report to the Trial Steering Committee.

All research at Queens may be the subject of an unannounced audit. The NI CTU will periodically audit the quality of the data from the trial, and the Trial Manager will audit the completion of the Case Report Forms to ensure that these are being completed as required.

To safeguard the scientific integrity of the
trial, data from this study will not be presented in public before the main results are published without the prior consent of the Trial Steering Committee. When the results of the trial have been established the findings will be reported in peer reviewed journals according to CONSORT guidelines and disseminated to all the study participants (CSDs) in a format that is accessible.

| 9 | Provide a more descriptive heading than ‘Other’ (page 23) | Other | Data on baseline equivalence  
In order to explore the extent to which randomisation has created two equal groups, the study will collect relevant data from participating social workers on their qualifications, experience and confidence in relation to complex assessments, and knowledge in relation to key areas (e.g. mental illness, intimate partner violence, substance misuse). These data will be collected from all social workers following a study briefing.  
The final sentence of this section has been moved to the end of the previous section, leaving this paragraph focused simply on the issue of group equivalence. |
|---|---|---|---|
| | | | Section on Implementation evaluation now ends:  
In order to explore the perceived impact of training, social workers in the experimental group will be asked to complete a second questionnaire following the SAAF training to explore its impact on their perceived knowledge and skills in assessment. |
In the analysis section, it would help to differentiate plans for each of the outcomes, since some are binary and some continuous.

**Inclusion of covariates**: In addition to the standard ITT, multivariate (regression) models will be estimated to examine the impact of covariates on outcomes. Baseline outcome measures (e.g. type of abuse, risk factors identified) will be included as covariates to allow for individual differences, and site differences will be modelled. Including information on covariates will allow us to examine moderator effects and to begin to unpick the mechanisms through which SAFF might impact on improved assessments and associated outcomes.

New paragraph added and slight change of wording to paragraph on Inclusion of Covariates (underlined here for ease of spotting)

*Outcome measures*: Some outcome measures are binary and some are continuous. Estimation methods will vary depending on whether the dependent variable is binary or continuous, but the logic of the analysis will in each case be the same.

**Inclusion of covariates**: In addition to the standard ITT, multivariate (OLS and logistic regression) models will be estimated to examine the impact of covariates on outcomes. Baseline outcome measures (e.g. type of abuse, risk factors identified) will be included as covariates to allow for individual differences, and site differences will be modelled. Including information on covariates will allow us to examine moderator effects and to begin to unpick the mechanisms through which SAFF might impact on improved assessments and associated outcomes.