Study protocol

Full title of project: Development and validation of a risk assessment tool for self-harm in prisoners

Acronym: RAPSS (Risk Assessment for Prisoners at risk of Self-harm and Suicide)

Acknowledgement and Disclaimer: This project was funded by the NIHR HTA programme (Themed call: A risk assessment tool to help identify prisoners at further risk of self-harm. Project number 16/159/09)

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Document history			
Version	Date	Editor	Comments
1	28/11/17	SF, AI, TM	Initial protocol submitted with full application
2	09/1/18	SF, AI, TM	Incorporated changes recommended by NIHR panel
3	30/4/18	SF, AI	Version agreed by NIHR panel

Summary of Research: *Please provide an expert summary of the project plan of investigation plus any additional points required to support statements made in the above sections, and include any key references required to justify the points made (e.g. in the use of particular outcome measures or methods of analysis).*

Rates of self-harm in prisoners are high and been increasing over the last few years. In 2015-16, there were 34,586 reported incidents of self-harm in 10,012 prisoners, a 27% increase on the previous year. One approach of the Prison Service to deal with these high rates has been to reduce the recurrence of self-harm, which is estimated at around 25% within 6 months. The current assessment of risk of recurrent self-harm on closure of a risk assessment management plan (also known as 'Assessment, Care in Custody and Teamwork' or 'ACCT') lacks a structured approach. Any reduction in self-harm will have large benefits for the Prison Service and NHS in reducing individual prisoner's physical and

psychiatric morbidity, attendant healthcare costs, possible disruption to release planning, and also improve the prison environment more widely. This project has three parts.

1. Development of a risk assessment tool

We will develop the tool using routinely collected information for reasons of feasibility and ease of translation. It will aim to identify risk of repeat self-harm within 3 months following the closure of an ACCT. Following consensus guidelines for prognostic research, we will create a statistical model based on a prespecified list of predictors based on previous evidence and new risk factors that will be tested in multivariable models. These factors will include socio-demographic, criminal history, and clinical ones, including those collected in the ACCT process, some of which are dynamic. In order to develop a robust model, we estimate requiring 150 new self-harm episodes in the 3 months post-ACCT. Assuming a self-harm rate of 20% in the 3 months post-ACCT closure, we anticipate needing information on 750 prisoners who have completed ACCTs for the development of the tool. We intend to extract these data either from an existing database of more than 12,000 ACCTs held by one of the co-applicants (this will require some new information being supplemented from paper review of ACCTs, prison healthcare records, and case files).

2. Qualitative study

We will then assess the acceptability of the new tool to relevant stakeholders (prisoners, clinicians and prison staff) based in three settings (one local/short-sentence; one long-stay; and one female prison) and examine barriers to implementation. Using action learning processes we will work with staff and prisoner groups over twelve months (via monthly sessions) to develop an implementation/operational pathway to embed the new tool within existing ACCT, post-ACCT procedures, and any other relevant processes.

3. Prospective study

After 18 months, when information from the qualitative study on feasibility and acceptability has been gathered, we will then conduct a validation study and prospectively test the tool's predictive ability in a cohort of prisoners at the end of their ACCTs. We will sample adult male and female prisoners on ACCTs from remand and sentenced prisons in contrasting regions. The sample size will be guided by the results from the development of the tool. The cohort of prisoners will be followed up for 3 months to identify new episodes of self-harm (or suicide) in custody. Measures of discrimination (sensitivity, specificity, positive and negative predictive value, C-index) and calibration will be reported in order to consider how such an instrument should be used in practice – to identify high risk individuals or screen out low risk persons.

Background and Rationale: *This section should include a brief literature review and how you expect to add to the body of knowledge with reference to current NHS policy and practice.*

Rates of self-harm in prisoners are high in absolute and relative terms. In 2015-16, there were 34,586 reported incidents of self-harm in 10,012 prisoners, a 27% increase on the previous year. There were 26,805 incidents of self-harm in male prisoners, up 31% on the previous year, equating to a rate of 3,280/10,000 prisoners. In women, there were 7,781 incidents of self-harm (a rate of 20,340/10,000), up 13% on the previous year (MOJ, 2016). Over the same period, there were 2,455 hospital attendances as a result of self-harm incidents, equivalent to a rate substantially higher than in community-based persons (MHF, 2016). The latest figures show that in the year to December 2016, there were a record 40,161 incidents of self-harm, up 7,848 from the previous year, which represents a 24% rise, and a 73% increase between 2012 and 2016. At the same time self-inflicted deaths have also increased. In the 12 months to March 2017, there were 113 self-inflicted deaths in English and Welsh prisons. This equates to a rate of 1.3 self-inflicted deaths per 1000 prisoners which is double the rate recorded in 2013 (MoJ Safety in Custody Statistics).

Self-harm rates in prisoners have continued to increase despite the ACCT process being introduced to address this (Prison Service Instruction 64/2011). Recent research showed that 28% of prisoners self-harmed in the 6 months following closure of the ACCT document (Horton, 2014). A particular problem identified was the lack of a structured approach for the assessment of risk of recurrent self-harm on ACCT closure.

Evidence explaining why this research is needed now: *Indicate the necessity for the research, both in terms of time and relevance.*

As described above, self-harm rates have risen in prisoners in England and Wales over the last few years. This themed call is timely since current clinical practice lacks the availability of a reliable instrument to predict risk of recurrent self-harm and link high risk prisoners to appropriate care pathways. Current practice in prisons for those that have suicidal ideation or have self-harmed is to place them on a suicide risk management plan, called an ACCT. Although this approach has proven effective in managing the immediate risk (while the ACCT lasts), evidence suggest that the risk of self-harm (and suicide) is high in the few weeks after the closure of the ACCT. Hence, devising a tool that can stratify risk after an ACCT is required.

The most successful prognostic tools in medicine are those that are underpinned by the strongest empirical base, including large representative samples for their development and validation, transparent reporting of methods and results, and parsimonious models that can be easily introduced into practice (Siontis, 2015). Guidelines recommend pre-specifying risk factors for investigation, how variables will be characterised, and pre-determined thresholds so that a range of performance metrics can be reported (Collins, 2015). It is important to highlight the challenges of developing and validating such instruments without an adequate sample size (Peduzzi, 1996; Harrell, 1996). In mental

health, one example is a scalable risk assessment tool for reoffending in released prisoners that was developed by two of the applicants. This was developed in around 30,000 prisoners and validated in more than 10,000 prisoners (Fazel, 2016). The tool is based on 14 routinely collected items, and performs as well as current approaches that can take many hours.

In the tool development, we plan to include risk factors based on research primarily in English and Welsh prisons (Marzano, 2016; Shaw, 2004; Humber, 2013): pre-existing mental and physical health problems, psychotropic medications, and specific questions from ACCTs on mental state, ongoing suicidal ideation, activities, and a further question about whether problems identified at the start of an ACCT have been resolved in the post-closure review (which typically occurs one week after an ACCT is closed).

The qualitative aspect of the proposed study is integral, since it will highlight challenges and barriers in the implementation of the tool, and consider how to overcome them. It will be based on research creating service models for the delivery of healthcare interventions in non-health settings, including a health and social care planning tool for older prisoners that some of the co-applicants developed (Walsh, 2014). Additionally, it is informed by research in other settings where tools have been created but not embedded into practice without clear pathways following different risk scores or categories.

Aims and objectives: *Please summarise the key aims and objectives of your project, and provide a concise statement of the proposed research*.

For the proposed project, we adopted the main aim outlined in the commissioning brief: "To develop a risk assessment tool to examine a change in risk factors for self-harm in prisoners following closure of an Assessment, Care in Custody and Teamwork (ACCT) process with the intention of reducing rates of self-harm through treatment." Our research question is based on this: “What is a valid, acceptable and scalable risk assessment instrument for self-harm in prisoners following an ACCT?” The first objective is to create a risk assessment tool that will identify the risk of repeat self-harm within 3 months following an ACCT closure. For this purpose, we will be using routinely collected data (prison/healthcare records, ACCT), thus reducing unnecessary costs and potential complexities in data collection. We will be using the latest consensus guidelines for prognostic research, in order to derive at a statistical model to predict repeat self-harm. The second objective is to assess the acceptability of this new tool to relevant stakeholders including prisoners, clinicians and prison staff, and examine barriers to implementation. In order to do this, we will conduct qualitative research using action learning processes. The final aim is to prospectively evaluate the instrument’s ability to predict risk of further self-harm (and suicide) in a cohort of prisoners at the end of their ACCTs. A sample of prisoners in London, Buckinghamshire, Lancashire and Yorkshire prisons will be followed up for 3 months to identify new episodes of self-harm (and also suicide) in custody.

Research Plan: *Outline the design of your research including the methods you plan to use; the target organisations, staff groups/professions, patient care group or disease area to be studied and brief*

details of the team involved in undertaking the research. Please ensure your fieldwork and methods are clearly connected to the aims and objectives and research questions you outlined earlier. The programme is interested in taking advantage of the growing utility of routine data (such as HES, GP records etc.), and would like investigators, where appropriate, to ask study participants to consent to long term follow-up (e.g. beyond the outcomes to be collected in the funded trial) using routinely collected data, and appropriate linkage to allow this data to be best used.

The guidance for this HTA themed call explained that the following elements should be followed: "Study design: The proposed research comprises 3 stages: i. Development of the risk assessment tool, ii. Qualitative research to assess acceptability to prisoners, clinicians and the prison service, and barriers to implementation, iii. A prospective cohort study to evaluate the predictive performance of the tool. There should be clear progression criteria between each stage."

The first part of the study involves the development of a risk assessment tool to predict the risk of self-harm in prisoners following the closure of their ACCT documents. We intend to develop the risk assessment tool (RAT) through the analysis of a large database covering 12,981 ACCT documents that was collected in a recent project by one of co-applicants (AP). We have had confirmation that the existing informed consent for research can apply to this project. We will need to extract more information from these documents and also routine medical and prison records for the development of the new RAT. We intend to develop a tool that will identify the risk of repeat self-harm within three months post-closure of any ACCT document. This time period was shown to be indicative of high risk and is supported by prison governors who have responded to our scoping enquiries. We will define self-harm to include any intentional self-poisoning or self-injury, irrespective of the degree of suicidal intent or underlying motive, which is used by the Her Majesty's Prison and Probation Service (HMPPS). We will create a statistical model to predict repeat self-harm based on a prespecified list of predictors. These will include a core set based on face validity, population-based studies of self-harm in England and Wales (Hawton, 2014), systematic reviews (Fazel, 2009), and other factors if they are shown to improve the predictive performance of the multivariable model. We will pre-specify categories for low, medium, and high risk of self-harm recurrence to inform ways in which model predictions could be used in practice. We will follow the latest guidelines for prognostic research (Collins, 2015).

The second part of the project is qualitative. It will assess the acceptability of the new tool to prisoners, clinicians, and prison staff, and examine barriers to implementation across the prison estate. It will work with prison staff and prisoners to develop an operational pathway that embeds the RAT within existing ACCT procedures. Importantly it will develop a pathway for how the scores from the RAT should be used in practice. This part of the study will be conducted by the Manchester part of the project team in three prisons in the north of England including a local short-sentence male prison, a long-stay male training facility, and one female prison. The Manchester team have existing links with these prisons and have extensive experience of conducting research in them. The team will convene a stakeholder action learning group comprising frontline and managerial prison officers and healthcare staff; prisoners and peer supporters (e.g. Listeners); and a range of other concerned individuals (carers, chaplaincy etc.). Over twelve months, each group will convene monthly to address

a particular aspect of implementation – e.g. training needs, defining the roles of each professional/peer within the process, timing of administration, and processes for instigating support based on RAT scores. Each group member will canvass opinions from their peers to bring a consensus view to meetings. This will ensure agreed processes reflect new ways of working likely to be acceptable to prisoners and the wider workforce thus increasing the likelihood of successful implementation.

The third part of the study will involve prospectively testing the tool's predictive ability in a cohort of prisoners at the end of their ACCT processes. The sample size will be guided by the results from the development of the RAT, although we have estimated that we will need to administer the tool to more than 500 prisoners. These prisoners will be followed up for 3 months to identify new episodes of self-harm (and suicide) in custody. We will sample prisoners on ACCTs from 16 prisons in 4 regions (London, Buckinghamshire, Lancashire and Yorkshire), including women and men, remand and sentenced prisoners, and those aged 18 and over. The RAT will be administered and its performance compared at two points – when the ACCT is closed and also at the post-closure ACCT reviews (to test additional dynamic factors) - by 3 researchers (two based in London/Oxford and one in Manchester) working independently from the ACCT team so that its performance will not be affected by changes to the management of prisoners based on the tool's score. We will report measures of discrimination (sensitivity, specificity, positive and negative predictive value, C-index) and calibration. This will allow for consideration of how such an instrument should be used: to identify high risk individuals or screen out low risk persons.

Health technologies being assessed: *Give a clear definition of the health technology to be assessed. The purpose of HTA is to assess the value of a health technology compared to best alternatives or, where none exists, against no intervention. Where there are established alternative technologies, these should also be defined carefully. Where the technology is subject to rapid change, details of how this will be dealt with in the project should be included.*

The commissioning call specified: "A risk assessment tool to examine change in dynamic risk factors for self-harm from the point of ACCT closure to fixed follow up points in order to guide treatment. The tool should be developed as part of the study and should include input from prisoners, staff and family."

We intend to develop a tool that will identify the risk of repeat self-harm within 3 months post-closure of any ACCT document. This time period has been shown to be indicative of high risk. We will define self-harm to include any intentional self-poisoning or self-injury, irrespective of the degree of suicidal intent or underlying motive, which is used by the Prison Service. We will create a statistical model to predict repeat self-harm based on a pre-specified list of predictors. These will include a core set based on face validity, population based studies of self-harm in England and Wales (Hawton, 2014), systematic reviews (Fazel, 2009), and other factors if they improve the predictive performance of the multivariable model. We will also pre-specify categories for low, medium, and high risk of self-harm recurrence to inform ways in which model predictions could be used in practice. We will follow the latest guidelines for prognostic research (Collins, 2015). At the first stage of our proposed project,

we will be developing the risk assessment tool from routinely collected information. At stage 2, we will be accessing the acceptability of the tool to prisoners, clinicians and the prison service, and evaluating barriers to implementation. Throughout the development and evaluation (stage 3) of this risk assessment tool, we will be consulting with our advisory group that consists of the co-applicants, the PPI group (prisoners and family) and representatives of the prison service (Safer Custody, NOMS).

Design and theoretical/conceptual framework: *Please provide a brief statement on the type of study design to be used, and the theoretical framing, concepts and models to be used.*

The theoretical framing of the study will be based on existing reviews and primary research on risk factors for self-harm and suicide in prisoners. The methods will be based on prognostic modelling in medicine to create and assess the performance of a risk assessment tool. A retrospective cohort will be used in the development of the tool and a separate, multi-centre, prospective cohort study will be conducted to evaluate its performance in an independent sample. We will follow recent consensus guidelines to design and report our study (TRIPOD guidelines). In the second part of the project, we will work with staff and prisoner groups over 12 months (via monthly sessions) to develop an implementation/operational pathway to embed the new tool within existing ACCT, post-ACCT procedures, and any other relevant health and social care support processes using action learning processes. Members of the current team (JS, JJS, TW) have successfully used action learning in previous criminal justice system research as a tool for understanding and improving professional practice (Noga, 2016), including the development of an assessment/referral mental health pathway in police custody and a multi-disciplinary care planning tool for older prisoners. Action Research principles involve the use of cycles of planning, observing, acting and reflecting to think through a problem and offer practical and implementable solutions (Zuber Skerritt, 2001, 2002). The action learning methodology has been considered a useful tool for encouraging multi-agency staff to critically reflect on their own service and on their working relationships with partner agencies (Ball, 2013; Dixon, 1998). We will aim to use multi-agency action learning groups to enable individuals in prison establishments, both professionals and peers (as well as the organisation itself), to learn from each other and develop more effective, practical solutions to the challenge of prediction of recurrent self-harm behaviours.

Target population: *Define the population from which the study sample receives the health technology concerned (or the control intervention where appropriate) e.g. women over 60, people with learning disability, people with advanced cancer.*

The target population is prisoners placed on an ACCT document whilst in prison custody. The ACCT document, currently in version 5, is a series of forms held together in an orange folder. It is 'opened' by staff working in prisons in response to concerns that an individual prisoner is at risk of self-harm or suicide. On the basis of the forms completed in the ACCT document, a 'CareMap Form' is completed in which a series of actions are considered to reduce the risk of harm occurring. An 'On-Going Record Form' records the conversations and observations of the person at risk. ACCT

documents are ‘closed’ when an individual is no longer considered ‘at risk’. The ACCT document is then typically held in a post-closure state for seven days during which it can be re-opened if further concerns arise, and a post-closure form is assessment is completed typically after 7 days. Our target population includes male and female prisoners, aged 18 and over, who are held in category A to C prisons.

Inclusion/Exclusion Criteria: *Please provide a detailed explanation of the inclusion/exclusion criteria.*

For stages 1 and 3: Inclusion criteria: Male and female adult prisoners (age 18 years old and above) that have been on an ACCT following a self-harm episode (including threats of self-harm). Prison categories (A to C). Exclusion: prisoners that have been on ACCT for reasons other than self-harm (e.g. vulnerability, violence). Note: there will be no face to face interviews with individual prisoners as information for the tool will be collected from ACCT documents already completed.

For stage 2: Inclusion criteria: any frontline and managerial prison officers and healthcare staff; prisoners and peer supporters (e.g. Listeners); and a range of other concerned individuals (carers, chaplaincy etc.) that are willing to participate in monthly meetings of the action learning group. Prisoner representatives should have at least 12 months to serve so that they can attend and contribute to meetings.

Setting/context: *Please describe the health service setting or context, in which the study will take place (such as the organisation or service type).*

The settings are prisons and university sites. The first part of the study involves the development of a risk assessment tool (RAT) to predict the risk of self-harm in prisoners following the closure of their suicide risk management plans (or ACCTs). The RAT will be developed primarily through the analysis of a large existing database of ACCTs. Data extraction will be undertaken in York (where the ACCTs are held) in conjunction with a local prison (in order to access medical and prison records) and then the tool will be developed in Oxford (where the PI and statistical lead are based). Linkage of the individuals on whom these ACCTs were completed to the prison data management system will be required to determine whether individuals have been released and to identify self-harm episodes in the 3 months post-ACCT. We anticipate that the data extraction and linkage will require two trained Research Assistants, one in York (data extraction and linkage) and one in Oxford (to do the analyses). Data will be transferred to the Department of Primary Care Health Sciences in Oxford for analysis and development of the RAT.

The second part of the project is qualitative in nature. It will assess the acceptability of the RAT to prisoners, clinicians, and prison staff as well as examine barriers to implementation. This part of the

study will be conducted by the Manchester co-applicants in 3 prisons and involve monthly focus groups based at the Division of Psychology and Mental Health at the University of Manchester.

The third part of the study will involve prospectively testing the tool's predictive ability in a cohort of prisoners at the end of their ACCTs in 16 prisons. The risk assessment tool will be administered and scored by three Research Assistants (two based in Oxford/London and one in Manchester). A consecutive sample of prisoners who have started ACCTs will be asked for consent, and then their ACCT documents and postclosure ACCT reviews used to score the RAT (independently of the prison staff and clinical teams). All selfharm episodes in the subsequent 3 months will be identified from central Safer Custody statistics (so that any prison transfers are accounted for). We anticipate that this part of the study will require the Research Assistants to have access to the prison sites for 12 months each. These data will be transferred to Oxford for analysis.

Search strategy *(in the case of projects involving evidence synthesis): Provide details of the body of existing evidence that will be covered and access arrangements (e.g. use of databases, hand-searching, communication with authors, etc.).*

N/A

Sampling: *Please describe for all projects your approach and rationale for sampling or selecting research sites and subjects. For quantitative studies, if appropriate, state the required sample size, giving details of the estimated effect, size, power and/or precision employed in the calculation where applicable. You should also provide estimations of recruitment and retention rates.*

Development of Risk Assessment Tool: In order to develop a tool with adequate statistical power, we estimate that 10 'events' (or new self-harm episodes in the 3 months post-ACCT) will be required per predictor variable (Peduzzi et al., 1996), and we anticipate testing 15 predictors for possible inclusion in the tool (a total of 150 events). Assuming a self-harm rate of 20% in the 3 months post-ACCT closure (Horton et al., 2014), we estimate that we will need information on 750 prisoners who have completed ACCTs.

Prospective Study: Sample size estimates for the prospective study are likely to depend on the performance of the risk assessment tool during model development. A formal assessment of sample size requirements will therefore be made after this phase is complete; however, some indication can be given at this stage. A simulation study recommended ballpark minimum figures of 100 events for validating a clinical prediction rule derived using a logistic regression model (Vergouwe et al., 2005). This conclusion was broadly supported by another, more recent, simulation study (Collins et al., 2016). The factor that influences power is the number of self-harm episodes, rather than the total sample size. We therefore anticipate including enough individuals to obtain a minimum of 100 self-harm episodes to adequately assess the performance of the risk assessment tool prospectively. Assuming the same self-harm rate of 20% in the 3 months post-ACCT closure, this equates to a

minimum of 500 prisoners who have completed ACCTs. The total sample size will be adjusted downwards should the self-harm rate be found to be higher than 20%.

The details of our sampling sites are provided elsewhere. In brief, we will recruit from a variety of Category A to C prisons, both in the South and the North of England. We will not be interviewing prisoners. Our data will be extracted from the ACCT documents of prisoners that have been on an ACCT following a self-harm episode (or threat of), which will be supplemented by information from medical and case files. Data will be collected at the point of the ACCT closure, post-closure review, and the participants will be followed up for 3 months for the outcomes of self-harm or suicide.

Data collection: *Please describe the data you plan to collect. Depending upon your study design and methodology, you may need to explain what data collection instruments or measures you plan to use and whether you will be using instruments already developed and tested elsewhere or instruments which you develop as part of this project. For example, where cost or outcome data is to be collected, you need to make clear and justify your approach to defining and measuring the costs or outcomes in question. You should make clear the link between the data collected and the research questions outlined earlier.*

We intend to collect data on a range of static and dynamic variables in developing the RAT. The static variables include age, index offence, duration of imprisonment, nature of current self-harm, medical diagnoses, medications, and the number and recency of prison transfers during the current prison stay. These will be collected through a paper review of a selection of the ACCT documents in the existing database and by linking them with SystmOne medical records (also held inside the prison) and NOMIS (central prison database). These can be accessed via one prison, as SystmOne and NOMIS are national databases available in all prisons. Medications may act as a proxy for diagnosis or severity, but will be assessed carefully due to the increased risk of medication diversion in prison and off label prescription.

Dynamic variables will include the length of time that a prisoner was on an ACCT document; the case reviewer's score of the patient's risk after each review (low, medium, or high); how many ACCT reviews were held; and the reason the ACCT document was initially opened (contained in the Concern and Keep Safe Form). The latter will be compared with the Post Closure Review form that has an item asking whether the problems leading to the opening of the ACCT have been resolved. We will also look at whether the individual has been referred and seen by mental health services during the ACCT process by examining SystmOne medical records.

There are dynamic variables in the Post Closure Form but these are not collected earlier in the ACCT process in a structured manner and hence it is not possible to know if they have changed during the process. This also applies to the CAREMAP Form, part of the ACCT document, which includes information on the problems, resources, goals, and level of risk. Based on preliminary discussions with prison officers, dynamic variables that typically are addressed in this form include family

support, financial problems (including debts to other inmates), immigration issues, and the prisoner's mental health, but it remains unclear whether there is a structured and reliable way to investigate them for the purposes of this study. Nevertheless, we will investigate the possibility of using these variables by looking at a small subsample of ACCTs and seeing if this information is reliably collected in a form that can be used for tool development.

Data analysis: *Please describe how you plan to analyse the data you have collected. Depending upon your study design and methodology, you may need to explain what quantitative statistical methods you plan to employ, your methods for qualitative data analysis, and your approach to combining data from multiple methods or sources.*

Development of Risk Assessment Tool: We will use time-to-event models to estimate the probability of an episode of self-harm following ACCT closure. Specifically, we will investigate using hazard rate model to allow for possible time-varying effects of dynamic risk factors (Thomas and Reyes, 2014). Risk estimates will be available at time of ACCT closure and subsequently. At the time of the post-ACCT interview (expected to occur between one week and one month after ACCT closure), additional dynamic variables will become available that may affect risk estimates even if not sufficient to trigger a new ACCT. We will therefore adapt our risk prediction model at the time of post-ACCT interview using model extension methods to incorporate additional covariates (Steyerberg, 2009, Chapter 20.2). Risk information will be presented numerically in the form of a probability of a self-harm episode within a fixed period of follow-up following closure of ACCT of following post-ACCT interview, and in relation to a probability threshold indicative of high risk (to be prespecified as part of the research project). Probabilities will also be expressed conditional on the length of the post-ACCT period that has already elapsed, to allow for the likely non-linear decline in risk over time, the initial 30 days after ACCT closure being a particular high-risk period for self-harm (Horton et al., 2014). This will also enable for the risk model to be used dynamically over time. Development of the RAT will use multiple imputation for missing risk factors and incorporate measures of internal validation to prevent model over-fitting, methodology we have implemented in previous work (e.g. Fazel et al., 2016). To check reliability of data extracted from paper files, we will extract a subset of 20 files by two people (one of them the research assistant and the other co-applicant AP).

Prospective Study: Our approach to prospectively assessing the performance of the tool will follow previously published guidelines (Royston and Altman, 2013, Su et al., 2016). Individual-level diagnostic performance of the tool (without adjustment of the model coefficients for the new population) will be summarised at 3 months post-ACCT closure using measures of calibration and discrimination including sensitivity, specificity, the cindex, and the calibration slope and intercept. Missing predictors will be imputed using multiple imputation. We will follow published guidance on reporting validation study results (the TRIPOD checklist: http://www.tripod-statement.org/TRIPOD/TRIPOD-Checklist). As data will be already collected as part of routine ACCT processes and medical records, a separate reliability study is not envisaged.

Dissemination and projected outputs: *Please describe the main knowledge products or outputs from your research and how they will be presented, disseminated and used. State how you plan to promote knowledge mobilisation so that the findings from the research impact on the management of health services and to improving practice and service delivery in the NHS.*

The primary objective of this research is to develop and validate a risk assessment tool to predict the likelihood of self-harm following the closure of ACCT documents in prisoners in England and Wales. As mentioned above, nearly one third of prisoners will go on to self-harm again within six months of the closure of their ACCT document (Horton 2014). This has significant implications for the criminal justice system and public health. Alongside the physical injuries arising from self-harming behaviour, the psychological distress of staff, prisoners, and their families also needs to be considered. This leads to additional resources being required to escort prisoners to hospital, increased referral rates to prison mental health inreach teams, and days off work for staff due to stress. All this impacts on the capacity of the prison to provide a stable environment and rehabilitative possibilities. If the research succeeds in developing an effective risk assessment tool that accurately predicts who remains at risk of further self-harming behaviour following the closure of their ACCT, there is the potential for significant resource savings for the criminal justice system as well as reducing distress for those involved. Future work can investigate how to link more accurate risk stratification into effective care pathways to improve risk management, and also by potentially screening out low risk persons, it may free up resources.

We are planning to publish two journal articles – one on the qualitative study, and one based on the development and validation of the tool. We have included open access costs in our application so that our findings are accessible to criminal justice (who will not have academic journal subscriptions). We intend to make conference presentations at one prison health conference and one suicide research meeting so that the findings are disseminated to individuals and organizations involved in prison health and suicide prevention. We also will present our findings to prison charities in one event for third sector organizations in the UK (e.g. Prison Reform Trust, Howard League). SF, KH and JS have existing links with the Independent Advisory Panel on Deaths in Custody, and presented to the panel previously – we will do so again. In addition, our PPI representatives will disseminate our results to POPS, prison charities and via newsletters to involved prisons.

We will also present the main findings to the prison service via the annual Training College seminar (where SF and KH have presented previously). This meeting is attended by many prison governors and prison officers. SL will present the results to internal events at the Ministry of Justice and Safer Custody. We will disseminate the validation findings and the tool via the Royal College of Psychiatrists Quality Network, which will provide one route to inform prison psychiatrists in England and Wales about the tool. We will use social media (Twitter, LinkedIn) to enhance dissemination. We endeavour to present interim results to local academic meetings, in Oxford, London, and Manchester. We will liaise with the NIHR communications team for advice on other means of dissemination that could increase the impact of our research and we will also work with the University of Oxford press office.

Plan of investigation and timetable: *Please provide a concise summary here of the project plan of investigation, preferably in the form of a monthly project timetable showing the scheduling of all key stages in the project, their expected durations, and the timing of key milestones throughout the project including the production of outputs. Please ensure your timings (e.g. time allowed for securing ethics/governance approval, for undertaking data collection and analysis, and for reporting and writing up) are realistic. This timetable will be an important aspect of the monitoring framework during the life of the project.*

The proposed duration of our project is 36 months; with a planned start date on 1st September 2018 and completion date the 31st August 2021. As soon as we have the approval for the funding of our project, we will advertise for the Research Assistants recruitment and will start the applications for all relevant approvals (ethics approval and NOMS-safer custody approvals). Our project will comprise of three stages:

Stage 1: Development of risk assessment tool

Duration: 1 year

Process: Extraction of routinely collected information. The most reliable source of static risk factors is OASys (information collected by NOMS/HMPPS). We will supplement this with information from existing ACCT documents and healthcare records. We will consider all demographic, criminological and clinical factors that are associated with risk of self-harming/suicide. We will use data from ACCT documents on male and female prisoners already collected. We will create a statistical model to predict repeat self-harm based on a prespecified list of predictors that will include a core set based on face validity, population-based studies of selfharm in England and Wales and systematic reviews, and other factors if they improve the predictive performance of the multivariable model. We will also pre-specify categories for low, medium and high risk of self-harm recurrence to inform ways in which model predictions could be used in practice, following the latest guidelines for prognostic research.

Outcome information: Self-harm (first episode) in the 3 months post-ACCT closure

Prisoner numbers: 750 (assuming 15 predictor variables being tested in the final model, 10 prisoners per predictor variable and 20% event rate post-ACCT)

First progress report to be submitted to NIHR HTA at 6 months of the start of the project and second progress report at completion of Stage 1.

Stage 2: Qualitative research to assess acceptability to prisoners, clinicians and prison service

Duration: 1 year

Methodology: Action learning processes. This part of the project will assess acceptability of the new tool to relevant stakeholders including prisoners, clinicians and prison staff and examine barriers to implementation. This process has been previously used successfully by members of the current team to operationalise a newly developed health and social care planning procedure in prison and a mental health and risk assessment tool in police custody. In each of three prisons (one local/short-sentence,

one long-stay, and one female), we will convene an action learning group comprising frontline and managerial prison officers and healthcare staff, prisoners and peer supporters (e.g. Listeners), and a range of other concerned individuals (carers, chaplaincy etc.). Over twelve months, each group will convene monthly to address a particular aspect of implementation - for example, training needs, defining the roles of each professional/peer within the process, timing of administration and processes for instigating support based on results of the tool. Each group member will canvass opinions from their peers, bringing a consensus view to meetings to ensure agreed processes reflect new ways of working likely to be acceptable to the wider workforce, thus increasing the likelihood of successful implementation. We will develop pathways based on different risk assessment scores so that those using the tool will know how to link the tool's outcomes with best practice.

A third progress report will be submitted to NIHR HTA at 18 months from the start of the project (6 months after the start of Stage 2) and fourth progress report at completion of Stage 2.

Stage 3: Prospective cohort study to evaluate predictive performance of the tool

Duration: 18 months

Methodology: Prisons to participate: 10 London, 3 Buckinghamshire and 2 Manchester and Leeds prisons. These prisons cover male and female prisoners, both adult and adolescents/young adults, that are either on remand or sentenced. The sample size will be guided by the results from the development of the tool.

Data collection: Three Research Assistants (one based in Manchester, and two based in Oxford/London) for 12 months. Tool administered independently at two points – at the closure of the ACCT, and also at ACCT post-closure reviews (to test whether dynamic factors incrementally improve performance). All prisoners will be followed up for 3 months using Safer Custody self-harm and suicide data.

Data analysis: One of RAs (based in Oxford) will assist with data analysis, supervised by statistician. Measures of discrimination (incl. sensitivity, specificity, positive and negative predictive value, C-index) and calibration will be reported.

Finalizing instrument according to prospective study.

Final report to be written.

Six-monthly progress reports will be submitted to NIHR HTA.

Project management *All project proposals should include details of how the project will be managed. For projects involving a number of institutions or component parts, effective project management is essential to ensure the work is completed within the planned timeframe. You should set out how joint applicants in different institutions will communicate and monitor progress of the project.*

The CI (SF) will be responsible for the overall Project Management, with some responsibilities being delegated to co-applicants. The CI will be responsible for the research governance and, with the assistance of AI, organising and facilitating advisory group meetings. The CI will monitor progress and achievement of milestones. For the validation study, AP will supervise one of the RAs (who will lead on extracting the data) and TF the other RA (who will lead on data analysis). The CI and co-applicants involved will be in monthly contact via meetings, teleconferences and email. TW will supervise the qualitative part (stage 2). For stage 3, Jenny Shaw and Jane Senior will coordinate the validation study at northern prisons, and AI and TM at the southern sites; the 3 RAs will be primarily supervised by Jenny Shaw and AI, respectively. One of these RAs will also assist with data analysis, and the analytic part of stage 3 will also be supervised by TF and SF. Any delays or change of plans will be discussed with the research team at first and subsequently brought to the advisory group meetings prior to notifying the NIHR. The advisory group will consist of the co-applicants and will include PPI, other Safer Custody, NOMS, and the Prisons Quality Network representatives and will meet every 6 months (in person or via teleconference). The CI will arrange an introductory meeting with the team, which will allow for agreed allocation of tasks and timelines. The CI will be responsible for coordinating write-ups and the timely submission of progress reports and the final report. He will also be responsible for disseminating to the research team and the advisory group (including PPI) any feedback from the NIHR, so that action is taken in an efficient and timely manner. The CI will take overall responsibility for the design, conduct, monitoring and reporting of the study. TF (senior medical statistician) will have the responsibility for the statistical component of the study. CI will ensure that the standards of the protocol, transparency, clear and supportive management are maintained throughout the project. The CI will be responsible for the finances of the study. The CI and co-applicants will have shared responsibility for the dissemination of the project findings to a broad range of audiences including clinicians, managers, commissioners and the wider public (through, e.g., charities). The CI will have the responsibility to provide copies of all project outputs to the NIHR at least 28 days before presentation/publication.

Approval by ethics committees *Outline the ethical issues and arrangements for handling them. Consider when the project requires approval by an ethics committee. If there is development work that is essential before you intend to apply for ethics approval, state this and make the timescales clear in your plan of investigation and project timetable. The funding board will consider this in detail and consider whether to offer staged funding. If you are using patient information from an existing database, you should check whether the patients have given their consent for their data to be included in that database for research purposes, or if not whether the database is exempt under Section 60 of the Health and Social Care Act 2001. Please note, if your application is successful, funding will not be released until all approval documents have been submitted to the programme.*

Existing ethics approval covers the development of the tool. The qualitative part of the project does not involve direct contact with current prisoners, and will require university ethics approval. As the validation study (stage 3) involves prisoners and involves access medical records, we will apply for ethics approval by the NHS Research Ethics Committee and approval by Her Majesty's Prison and Probation Service National Research Committee. The application for ethical consent to these bodies takes place simultaneously through the Integrated Research Application System (IRAS), for which we have received an application number. We anticipate that it will take around 6 months from a

notification of a successful application to obtain the relevant ethical approvals necessary to conduct the study.

Patient and Public Involvement *NIHR expects involvement of patients, carers or the wider public in the research it supports. You are encouraged to consider whether the scientific quality, feasibility or practicality of a proposal can be improved with Patient and Public Involvement.*

Co-applicant JB, a former service user at the Cassel Hospital, has experience in both service user-led research and involvement in general research studies. She was involved in development of the outline application. As a member of the project development team, she has commented and contributed to study design and writing the application. She advised on the PPI strategy, suggested ways in which prisoners and staff might be involved in the research, and shared how PPI can be best integrated into the project. JB will receive appropriate further training as part of her role on the project. We have also approached Partners of Prisoners (POPS), a Manchester based group established in 1988 by family members of prisoners, to advise and assist with the project. In addition to providing support services, POPS is involved in service development and strategic planning groups. We envisage that two representatives of POPS will be attached to this project, contributing to discussions involving the development and implementation of the risk assessment tool. Our PPI participants will communicate with the wider POPS group and apart from their advisory role in all stages of the project, they will be involved in the dissemination of the results.

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