UNIVERSITY OF LINCOLN

PROTOCOL

Measuring and improving the health and quality of healthcare for people on probation: Developing data collection and quality indicators

Developing data collection and quality indicators for probation

Protocol Version 2
Date 06.09.21

IRAS Project ID	276675
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Sponsor ID	21003
Funder	NIHR, Research for Patient Benefit Programme

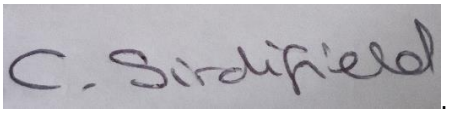
SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement(s).

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:  ..... Date: 06/09/21.

Name: Dr Coral Sirdifield

STUDY/TRIAL CONTACTS

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FUNDER DETAILS

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
	National Institute for Health Research

STUDY SUMMARY

Study Title	Measuring and improving the health and quality of healthcare for people on probation: Developing data collection and quality indicators
Study Design	Multi-methods study • Self-administered survey • Focus group • Online surveys • Systematic review
Study Participants	• People on probation in four National Probation Service Local Delivery Units (surveys of health and social care needs) • People with lived experience of the criminal justice system (focus group) • Experts working in the health and justice field (expert panel to complete online surveys and participate in discussion for development of quality indicators)
Eligibility Criteria	• Surveys: Anyone aged 18+ in contact with probation in the selected Local Delivery Units with sufficient understanding of English and capacity to consent to complete a survey • Focus group: Anyone with lived experience of the criminal justice system, including being on probation • Expert panel: Experts working in the health and justice field – likely to be from Public Health England, Clinical Commissioning Groups, Health and Wellbeing Boards (commissioners), the Ministry of Justice, HM Inspectorate of Probation, and the National Probation Service
• Planned Sample Size	• Survey of health and social care needs n=3000-4000, estimated response rate of 10% (minimum) • Focus group n=5-10 • Expert panel n=10-15
Study Duration	Participant duration: • Survey on health and social care needs: 15 minutes • Focus group for development of quality indicators (service user panel): 1.5 hours • Expert panel: online survey for development of quality indicators (expert panel) – 20 minutes • Completion of online survey to rate quality indicators (expert panel) – 25 minutes • Discussion of final list of quality indicators (expert panel) – 1 hour Total study duration: 19 months
Objectives	This research aims to support evidence-based commissioning of appropriate and accessible services for people on probation through the following objectives. To: 1. Improve the measurement, understanding and recording of the health and social care needs of people on probation, and their patterns and experiences of service access (improving data collection) 2. Develop quality indicators for the quality of the healthcare that people on probation receive
Outcome Measures	Overview of health and social care needs and the extent to which they are being met by current service provision Creation of quality indicators

Data Analysis	Surveys of health and social care needs: Data will be entered into a database for analysis by a medical statistician. No names will be entered into this database. Hard copies of the survey and participant information resources will be kept in a locked metal filing cabinet. Digital versions will be kept in files that are only accessible to members of the research team on the University of Lincoln network or OneDrive. Demographic data will be used to determine the extent to which survey respondents reflect the population within the national probation caseload. The survey data will be weighted to better represent the national population in terms of its demographic profile using an appropriate weighting methodology - propensity score weighting. Data will be analysed using descriptive statistics to show a) the prevalence of needs, and b) patterns of service access and the extent to which needs are being met. Mixed effects models (also known as multi-level models) will be used to predict health and social care needs based on service user and area characteristics. Systematic review: Existing quality indicators will be extracted from the included papers for inclusion in the online surveys Online surveys for development of quality indicators: Data from the first survey will be exported into Excel and then entered into NVivo (qualitative data analysis software) and analysed using thematic analysis. Ratings from the second survey will be exported into Excel for analysis. This will simply involve calculating the mean score for each indicator. Service user panel focus group: Participants will be interviewed using a semi-structured interview guide co-designed by the Peer Researchers. The focus group will be digitally recorded, transcribed verbatim, and analysed in NVivo using thematic analysis with support from the Peer Researchers. The focus group will be conducted face-to-face or online. Online/telephone interviews for feedback on administration of survey: Participants will be interviewed using a semi-structured interview guide. Interviews will be recorded via a digital recorder or via Microsoft Teams, transcribed verbatim, and analysed in NVivo using thematic analysis.

KEY WORDS

Probation, healthcare, social care, health needs, quality indicators

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LIST OF ABBREVIATIONS

ADHD	Attention Deficit Hyperactivity Disorder
AE	Adverse Event
AUDIT-C	Alcohol Use Disorders Identification Test—Consumption
A&E	Accident and Emergency
BAME	Black, Asian and Minority Ethnic
CANSAS-P	Camberwell Assessment of Need Short Appraisal Schedule - Patient
CCG	Clinical Commissioning Group
CF	Consent Form
CI	Chief Investigator
CORE-10	Clinical Outcomes Routine Evaluation - 10
CRF	Case Report Form
DAST-10	Drug Abuse Screening Test - 10
EudraCT	European Clinical Trials Database
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
JSNA	Joint Strategic Needs Assessment
LDU	Local Delivery Unit
LIH	Lincoln Institute for Health
NHS	National Health Service
NIHR	National Institute for Health Research
NPS	National Probation Service
NRC	National Research Committee
OASys	Offender Assessment System
PI	Principal Investigator
PIS	Participant Information Sheet
QI	Quality Indicator
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SPSS	Statistics Package for the Social Sciences
TMF	Trial Master File
UoL	University of Lincoln

STUDY MANAGEMENT

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor of the study is the University of Lincoln.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

STUDY MANAGEMENT COMMITTEES

Study Steering/Management Group

The Study Steering/Management Group shall meet three times face-to-face during the study (although this may be via Teams where required), with tele-conferences in between as required to ensure all practical details of the study are progressing well and working well and everyone within the study understands them.

STUDY BACKGROUND and RATIONALE

The Problem

There are over 250,000 people in contact with probation in England and Wales. There is a lack of systematically collected good quality data on their health and social care needs, and their patterns and experiences of service access. The limited research available suggests that they have a higher level of health need than the general population. Indeed, one study found that people on probation's "subjective mental and physical health and functioning was significantly poorer than that of both the general population and manual social classes" [1]. However, this group often encounter barriers to accessing care, including falling through gaps between services due to a lack of appropriate provision to meet their needs. Failure to systematically identify and address needs is costing lives; the number of deaths amongst those on probation is increasing [2]. Additionally, there are no specific indicators for the quality of care that this group receive. These individuals are often overlooked; their voices seldom heard.

The lack of quality indicators and research-informed systematic assessment of need makes it difficult to:

- Identify the needs of those experiencing many of the negative social determinants of health, including for Joint Strategic Needs Assessments
- Provide up to date data on these needs and the extent to which they are being met by current service provision to commissioners and policy makers
- Achieve evidence-based commissioning of appropriate and accessible services
- Ensure that probation staff identify need and facilitate access to services/assessment if required, and
- Identify high quality service provision and areas for improvement or intervention

The importance of the research

Providing appropriate and accessible health and social care for people on probation is important, not only to improve the health of a marginalised group and save lives; but also, because this will produce a 'community dividend' by reducing health inequalities, improving community safety; and reducing reoffending, the number of victims and the costs associated with this [3,4].

Probation services are were provided by the National Probation Service (NPS) and Community Rehabilitation Companies. However, they have now been reunified, and are viewed as increasingly important as the government wishes to move away from ineffective short custodial sentences. The proposed research is timely as:

- There is emphasis on improving care for this group in the NHS Long Term Plan
- Reunification:
    - Enables us to improve needs assessment for the whole probation population by working with just one organisation
    - Provides an opportunity for NPS staff to innovate, and argue for changes to data collection systems, and resources to support these, as part of the developing digital and data strategy

Conducting this research will:

- Introduce systematic methods of screening and quality assessment that can be incorporated into routine systems and practice - benefiting probation staff, service users, and commissioners through improving understanding of the health and social care needs of probation clients and the quality of the care that they receive

- Enable all probation Local Delivery Units (LDUs) to share reports detailing the current needs of their caseload and measures of the quality of care received to their local Health and Wellbeing Board(s)
- Benefit people on probation, by reducing barriers to providing evidence-based care for them
- Enable identification of where processes and outcomes are suboptimal (e.g. there is unmet need or no process is in place for supporting access to a particular service), where they work well, and where interventions may be needed to improve processes and outcomes e.g. improved service user experience.

Review of existing evidence

Internationally, people on probation are identified as a marginalised and underserved group that experience many of the negative social determinants of health such as unemployment, homelessness, and low levels of education. From the limited research that has been conducted, we know that whilst they are not a homogeneous group, there is a higher prevalence of mental illness, drug and alcohol misuse and smoking than in the general population. They are at high risk of suicide, self-harm, and of contracting communicable diseases [2, 5-9], with one report showing that 46% of female offenders had attempted suicide at some point, compared to 6% of the general population [10]. Increasing numbers of people are encountering the criminal justice system "due to poor mental health and the strain on mental health services" [10]. Much of this population have complex health needs – experiencing more than one health problem at any given time [6, 11, 12]. Needs may be particularly acute at certain times, such as the transition from prison into the community. Indeed, a substantial proportion of deaths are likely to occur within the first few weeks of release [10, 13, 14].

Consequently, it is important that probation staff have a systematic method for identifying need and that this is met through appropriate commissioning of partnership services. Whilst some research has taken place as detailed above, previous studies, including a recent systematic review that we conducted, have identified that there is a paucity of good quality and up-to-date research on the health and social care needs of people on probation [15, 16, 22]. As Bradley (2009) and Lennox et al., (2009) commented over a decade ago, there is still a need for research into the prevalence of different health problems within the probation population to inform commissioning [15, 16].

Recent NHS and probation policies recognise the importance of measuring and improving health and wellbeing and access to care as part of rehabilitation and reducing re-offending [17-21]. Contact with probation provides an opportunity to engage this underserved group. However, measuring and improving health and wellbeing and access to services, and providing evidence-based appropriate and accessible care for people on probation is problematic for a number of reasons:

A lack of understanding, measurement and recording of needs (limited data to inform commissioning)

The NPS use two main systems to record data about their caseload – NDelius, and the Offender Assessment System (OASys). We consulted with their Health Leads Group to ascertain what current routine data collection (as opposed to data collection for research) on health and social care needs covers. We found that data collection can be ad hoc and is rarely based on established screening tools. Therefore the data that are collected are unlikely to accurately reflect need. Moreover, little is systematically recorded about whether any identified needs are met, and these data cannot be easily compared to data for other populations. Data recorded elsewhere, for example in GP or prison healthcare records, are not routinely available to probation staff. Data available within probation are not always visible or accessible to health and social care commissioners [4]. Consequently, probation staff may not always recognise when there is need to facilitate access to services, and commissioning is rarely informed by data on probation clients' needs.

To improve this, we wish to introduce a method for systematic assessment of need using established screening tools which are recognised and understood by commissioners and providers. We identified which areas and tools to include in the assessment through consulting the literature, discussion with the NPS Health Leads Group, and analysis of their Health and Social Care Strategy. This enabled us to produce an approach that they feel is acceptable for use during and beyond the project.

A lack of quality indicators (QIs)

Secondly, there are no QIs to measure and improve the quality of the care that people on probation receive. QIs are used elsewhere, including within the criminal justice system, as an important method for assessing the quality of care and identifying areas for improvement. Preliminary proposals for such indicators have been made in previous research [22]. However, further development of these measures is needed.

A lack of evidence-based commissioning resulting in difficulties providing and accessing appropriate care

Thirdly, despite (albeit limited) data to suggest that people on probation have a high level and complexity of health and social care need, this group often encounter barriers to accessing care. Services are not always designed to address the complexity of need that this population experience – resulting in them falling through the gaps between services. Many people on probation encounter difficulties in accessing GPs, and both service users and probation staff struggle

to navigate a complex and ever-changing health landscape [4, 10, 22-25]. Consequently, many people on probation do not access services until they are at crisis point, often presenting to A&E, leading to higher costs for the NHS.

Commissioning of the majority of healthcare in England, including for people on probation, is the responsibility of Clinical Commissioning Groups (CCGs). Local Authorities also commission social care and have a non-mandated function as a condition of the public health grant to commission substance misuse services for the entire population in the community, including people on probation. However, around one in five CCGs mistakenly believe that commissioning healthcare for this group is the responsibility of NHS England (because they commission healthcare in prison and other places of detention) [26, 27].

Service provision should be based upon needs assessments providing a picture of the level of need within a population, a map of current healthcare provision and gaps in service provision, and priorities for resource allocation to meet the identified need [3]. Both CCGs and Local Authorities have joint responsibilities through Health and Wellbeing Boards to produce Joint Strategic Needs Assessments (JSNAs) which can include analysis of the needs of disadvantaged groups like people on probation. However, there are very few JSNAs that reference the needs of this group [4, 26]. Where they do so, there is often a prison within the CCG boundary. Reasons for this lack of focus may include the lack of easily accessible needs data.

In summary, routine data collection on health and social care needs and patterns of service access by the NPS is currently limited. If we are to improve the health and wellbeing of this deprived population, it is crucial that we improve assessment processes to provide an accurate picture of their needs, and patterns of service access. This is essential to inform probation practice, and enable evidence-based commissioning of services. We also need to develop QIs to enable us to examine the extent to which needs are being met, and whether appropriate processes are in place to support this. Doing these things would benefit patients through improved health and reduced health-inequalities, and would produce a 'community dividend' including a reduction in offending and avoidable use of crisis care. This would produce cost savings for the NHS.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

This project aims to support evidence-based commissioning of appropriate and accessible services for people on probation. We wish to improve data collection within probation around the health and social care needs of people on their caseload and the extent to which they are being met by current service provision; and to develop quality indicators for the quality of health and social care that this population receive.

PRIMARY OBJECTIVE

Improve the measurement, understanding and recording of the health and social care needs of people on probation, and their patterns and experiences of service access (better data collection)

SECONDARY OBJECTIVE(S)

Develop quality indicators for the quality of the healthcare that people on probation receive

OUTCOME MEASURES/ENDPOINTS

PRIMARY OUTCOME MEASURE/ENDPOINT

Overview of health and social care needs and the extent to which they are being met by current service provision

Creation of quality indicators

STUDY DESIGN

This is a multi-centre, multi-methods study involving:

1) Surveys of the health and social care needs of people in contact with probation in four probation Local Delivery Units (improving data collection) and telephone/online interviews to gather feedback around the administration of these
2) Development of quality indicators using the modified Rand method detailed by Van Engen-Verheul et al., (2011) [28], which includes the following:

a. A systematic review of the literature to identify existing quality indicators for health and social care in use in probation outside of England, or elsewhere in the criminal justice system
b. A service user panel focus group with individuals with lived experience of the criminal justice system – to support the development of quality indicators
c. Two online surveys with an expert panel of people working in the health and justice field. The first of these will ask participants what they think the characteristics of excellent health and social care for people on probation are, and how this could be measured (i.e. what they think good quality indicators would look like). The second survey will ask participants to rate a draft list of quality indicators compiled based on the findings from the systematic review, service user, and expert panels. The expert panel will be asked to rate these quality indicators on a 5-point Likert scale based on whether or not they have a clear link to outcomes for service users, can be a departure point for improvement actions, and are practical to implement. A mean score will be derived for each indicator. Participants will also be able to suggest additional indicators if they feel that something is missing
d. Finally, the expert panel will discuss the final list of quality indicators developed from the study to enable any final amendments to be made if needed.

DATA ANALYSIS

Surveys of health and social care needs and the extent to which they are being met by current service provision: data will be entered into a database by a Research Assistant for analysis by the Medical Statistician. Analysis is anticipated to take place in SPSS and STATA. Demographic data will be used to determine the extent to which survey respondents reflect the population within the national probation caseload. The survey data will be weighted to better represent the national population in terms of its demographic profile using an appropriate weighting methodology - propensity score weighting. Data will be analysed using descriptive statistics to show a) the prevalence of needs, and b) patterns of service access and the extent to which needs are being met. Mixed effects models (also known as multi-level models) will be used to predict health and social care needs based on service user and area characteristics.

Systematic review: Existing quality indicators will be extracted from the included papers for inclusion in the online surveys.

Service user panel focus group: Participants will be interviewed using a semi-structured interview guide co-designed by the Peer Researchers. The focus group will be conducted online and recorded, transcribed verbatim, and analysed by the research team in NVivo using thematic analysis with support from the Peer Researchers.

Online surveys for development of quality indicators: Data from the first survey will be entered into NVivo (qualitative data analysis software) and analysed using thematic analysis. Ratings from the second survey will be extracted into a database for analysis. This will simply involve calculating the mean score for each indicator.

Draft analyses will be presented at project steering groups, with additional work, or revisions being undertaken if needed following discussion at these meetings.

Notes will be taken in Word during the discussion of the final draft indicators, and used to inform any final changes to them.

STUDY SETTING

Surveys of health and social care needs and the extent to which they are being met by current service provision: Data will be collected across four probation Local Delivery Units containing a mixture of urban and rural areas. Feedback will be collected from probation staff via online/telephone interviews.

Systematic review: Will be conducted at the University of Lincoln.

Service user panel focus group: Participants will recruited by Revolving Doors Agency peer researchers, and the focus group will take place online or at a location selected by Revolving Doors Agency.

Online surveys for development of quality indicators (expert panel): These will take place online, with the final discussion taking place via (online) teleconference.

SELECTION OF PARTICIPANTS

ELIGIBILITY CRITERIA

Inclusion Criteria

Surveys of health and social care needs and the extent to which they are being met by current service provision: Any individual aged 18+ years that is on probation, in the community (including probation Approved Premises) in one of the Local Delivery Units selected for the study that probation staff believe has sufficient understanding of English to complete the survey, and capacity to provide informed consent

Online/telephone interviews: staff that have administered the surveys of health and social care needs.

Service user panel focus group: Individuals aged 18+ with lived experience of the criminal justice system, including being on probation with sufficient understanding of English and capacity to consent to participate in the focus group.

Online surveys for development of quality indicators (expert panel): Individuals working in the health and justice arena - we will approach National Probation Service Health leads, and individuals working in appropriate roles in Clinical Commissioning Groups, Public Health England, the Ministry of Justice, Health and Wellbeing Boards (commissioners), and HM Inspectorate of Probation.

Exclusion Criteria

Surveys of health and social care needs and the extent to which they are being met by current service provision: Individuals aged less than 18 years, individuals with insufficient understanding of English to complete the survey, individuals who do not have capacity to provide informed consent.

Online/telephone interviews: people that have not been involved in administering the survey.

Service user panel focus group: Individuals aged less than 18 years, or without relevant lived experience, or insufficient understanding of English or capacity to consent to participate in the focus group.

Online surveys for development of quality indicators (expert panel): Individuals that are not working in appropriate roles in the health and justice arena.

Sampling

IMPROVING DATA COLLECTION (SURVEYS OF HEATLH AND SOCIAL CARE NEEDS)

The research team have worked with a probation service Divisional Director to identify probation Local Delivery Units that contain a mixture of urban and rural areas, including one Local Delivery Unit with an above average proportion of people on probation from BAME groups (to facilitate inclusion of these groups in the research responses). Probation staff have a list of everyone that is on the caseload and based in the community (including within Approved Premises) in these areas, which they will use to notify the research team of the number of surveys required, and to track who has participated in the survey, who has declined to participate, and when reminders have been given.

All individuals in these areas will be invited to participate in the survey when they attend at probation premises, or by remote contact (telephone or online) if they attend less than once a month, or are not able to attend due to ongoing restrictions in relation to covid-19 - i.e. probation staff are not selecting participants, they are giving details of the study to all potential participants on the caseload.

An email will be sent via our probation co-applicant to all staff that may have played a role in administering the survey to ask for volunteers to participate in an online/telephone interview to provide feedback on what this was like.

DEVELOPING QUALITY INDICATORS

The service user panel will be recruited by Revolving Doors staff and their Lived Experience Peer Researchers from those involved in their Lived Experience research.

The expert panel will be recruited by the Research Team. A National Probation Service Divisional Director is part of this team, and will invite National Probation Service Health Leads to participate if they wish to. The research team already have a list of potential participants based in the other key organisations listed earlier in this form that they can invite to participate based on their appropriateness due to their roles within the health and justice arena. The study has already been discussed with members of some of these organisations, who have been supportive of the research proposed.

Size of sample

We anticipate that there will be 3000-4000 people on probation across the Local Delivery Units, all of whom will be invited to complete a survey. We anticipate that we will achieve a minimum return rate of 10% but will aim to achieve a higher rate (likely to be between 33% and 50%). This should give sufficient data to be able to complete the analysis set out above. We would like 5-10 staff to take part in online/telephone interviews to provide feedback on this.

We aim to recruit 5-10 people with lived experience of the criminal justice system for the focus group, and 10-15 people in appropriate roles in the health and justice field for the expert panel. This should be a manageable number of individuals and give us sufficient data to gain insight into service user views and experiences, and to ensure that a range of appropriate organisations are represented on the expert panel.

Sampling technique

Surveys of health and social care needs and the extent to which they are being met by current service provision: All individuals aged 18+ that probation judge to have sufficient understanding of English and capacity to provide informed consent in contact with probation and based in the community (including in probation Approved Premises) will be included in the sample.

Online/telephone interviews: An email will be sent via our probation co-applicant to all staff that may have played a role in administering the survey to ask for volunteers to participate in an online/telephone interview.

Service user panel focus group: A purposive sample of individuals meeting the inclusion criteria will be recruited by Revolving Doors Peer Researchers

Online surveys for development of quality indicators (expert panel): We will recruit a purposive sample of experts in the field. The research team specified a list of organisations that they would like to see represented on the expert panel in the funding application for this research, and will approach individuals from these organisations to participate.

RECRUITMENT

Potential participants for the survey on health and social care needs will be recruited from the probation Local Delivery Units selected for the study. The initial approach will be from a member of probation staff.

Each potential participant will receive an information sheet and consent form from probation staff either:

a) Face-to-face when they attend probation premises
b) Via email if the individual attends less than one per month, or covid restrictions are still in place so the individual is not being supervised in a probation office (i.e. an alternative such as telephone supervision is being used)
c) Via post, and potentially read to them over the telephone/online platform if covid restrictions remain in place, and a potential participant does not have access to email.

The individual will either read the information sheet and consent form their self, or it will be read to them by a member of probation staff. Decline or consent to participate will then be noted by probation staff. The participant will sign the consent form either in ink or as a typed signature (e-consent). Probation staff may ask for appropriate covid-related measures to be used such as use of a separate pen/hand sanitisation/quarantine of paperwork to fit with any local procedures in place at the time of administration.

After consent is taken, the survey can then be either self-completed with a member of probation staff present, or completed by a member of probation staff on the participant's behalf, with the staff member reading through it with the participant either face-to-face or via remote contact (e.g. phone/Microsoft Teams). This is to ensure that the study is as inclusive as possible. The survey will only be administered remotely if the participant has an appropriate (private) space in which to take part, and individuals will not be able to self-complete the survey and return it via email, as probation staff need to review the answers straight after it is completed.

Probation staff will use their judgement to select who has sufficient understanding of English to take part, and capacity to provide informed consent. It will be made clear to potential participants that taking part is voluntary and individuals

are free to withdraw at any time, without giving any reason, and without their legal rights or relationship with probation being affected. However, as participation is anonymous it will not be possible to withdraw data once submitted, as the research team will have no way of identifying individual participants.

If a member of probation staff completes the survey with a participant, they will already be aware of their answers. If the participant self-completes it at a face-to-face appointment, they will then hand it back to a member of probation staff, who will immediately review the answers to check if they indicate any increased risk of harm to self or others (e.g. feeling suicidal). In all cases, after the responses have been read by probation staff, they will then be placed in a pre-addressed freepost envelope for return to the research team.

Potential participants in online/telephone interviews for feedback around administration of the survey will receive an information sheet and consent form attached to an email sent to all relevant staff via probation.

Potential participants in the service user panel will be approached by Revolving Doors and given an information sheet and consent form to read and complete prior to participating. They will be recruited via their Peer Researcher/Lived Experience network.

Potential participants in the expert panel will be approached by a member of the research team by telephone or email (publicly available or provided after a telephone conversation on their public number), and given an information sheet and consent form to read and complete prior to participating. They will be selected based on having an appropriate job at an organisation that is relevant for inclusion in the research.

Participant Payment

Participants will not be paid to participate in the study.

CONSENT

Informed consent will be provided for the surveys of health and social care needs. A written or typed signature (e-signature/consent) will be provided on the consent form.

The recruiting Investigator (member of probation staff) will explain the details of the study and provide a Participant Information Sheet (and any other study related literature), ensuring that the participant has sufficient time to consider participating or not. Opportunity will be given to the participant to ask any questions they may have has concerning study participation. Every effort has been made to ensure appropriate readability for the information sheet, consent form and survey, which has been piloted with people with lived experience of the criminal justice system, but potential participants can also request assistance from probation staff to read and complete the forms if desired.

Individuals participating in the online/telephone interviews will provide written informed consent by returning the consent form to the member of probation staff inviting people to take part, who will then upload these to a shared file for the research team to see.

Similarly, potential members of the service user panel will provide written informed consent after receiving an information sheet and consent form from the research team about those elements of the study, either as a hard copy, or via an email from Revolving Doors Agency (wet ink signature/e-consent). In the case of the expert panel, the information sheet and consent form will be incorporated into the online survey, so consent will be provided as e-consent.

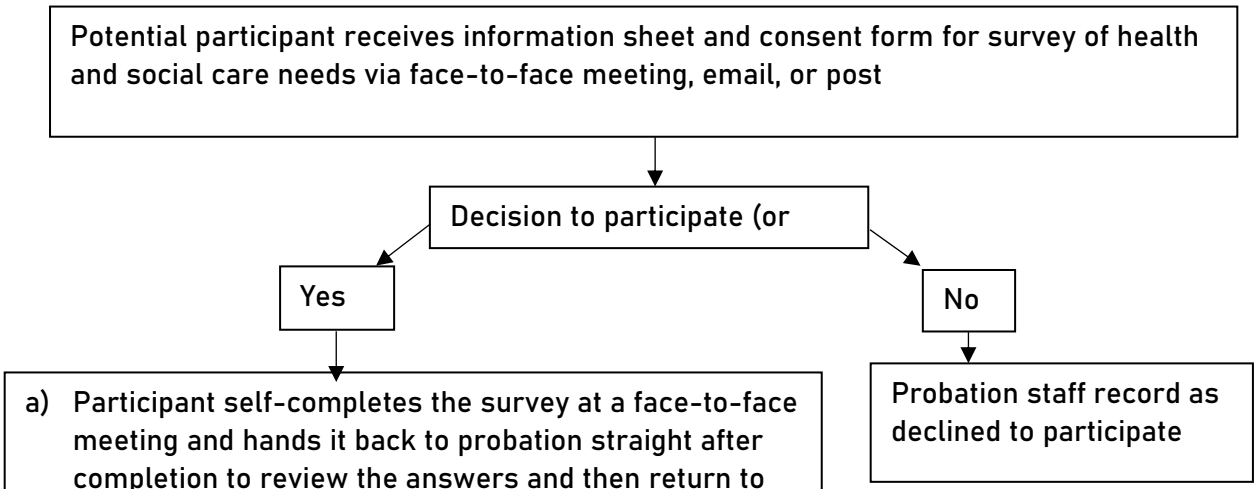
The process for obtaining participant informed consent for all elements of the research will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended consent form which will be signed by the participant.

STUDY PROCEDURES/REGIMEN

STUDY FLOWCHART

IMPROVING DATA COLLECTION (SURVEYS OF HEATLH AND SOCIAL CARE NEEDS)

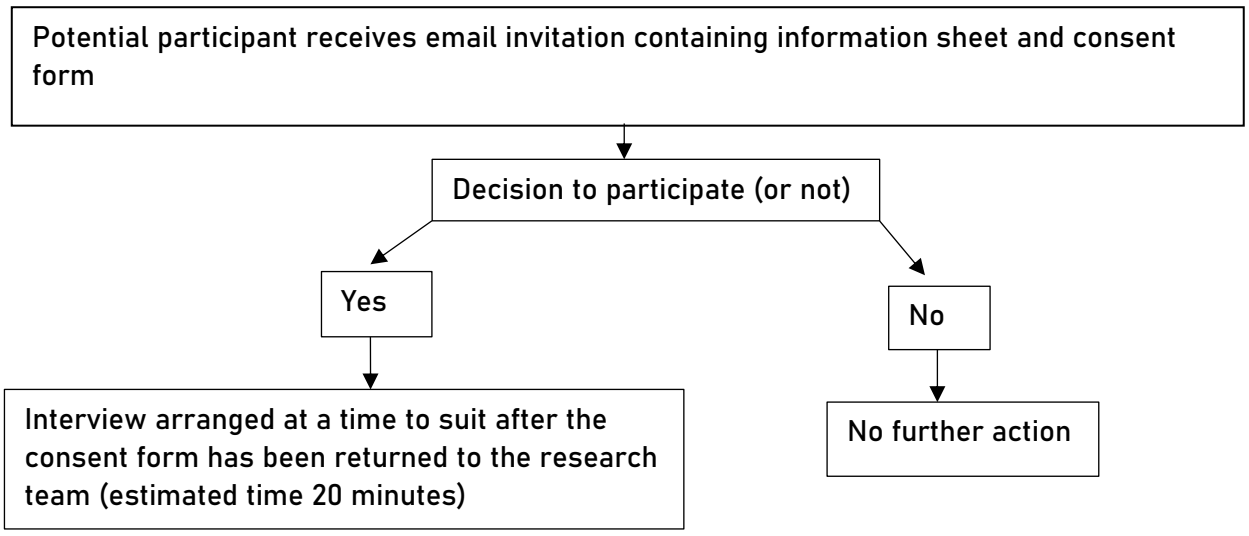


a) Participant self-completes the survey at a face-to-face meeting and hands it back to probation straight after completion to review the answers and then return to the research team via pre-paid envelope
b) Probation staff member records the participant's responses if needed due to lack of face-to-face contact, very low literacy levels, or covid restrictions meaning that contact is limited (estimated time 15 minutes). Then returned via pre-paid envelope

In both cases, the member of probation staff will ensure that informed consent is taken as either a wet ink signature, or e-consent, and will review the answers given to the survey straight after it is completed.

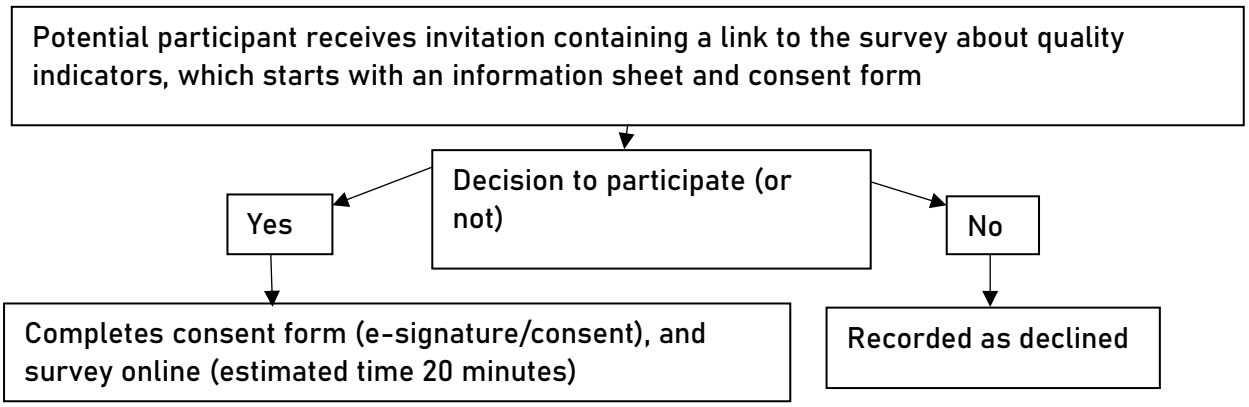
The invitation to participate may be followed up by probation if no response is received – two reminders will be given, but this will not be coercive. Paperwork will make it clear that non-participation will not affect relationship with probation

Online/telephone interviews for feedback

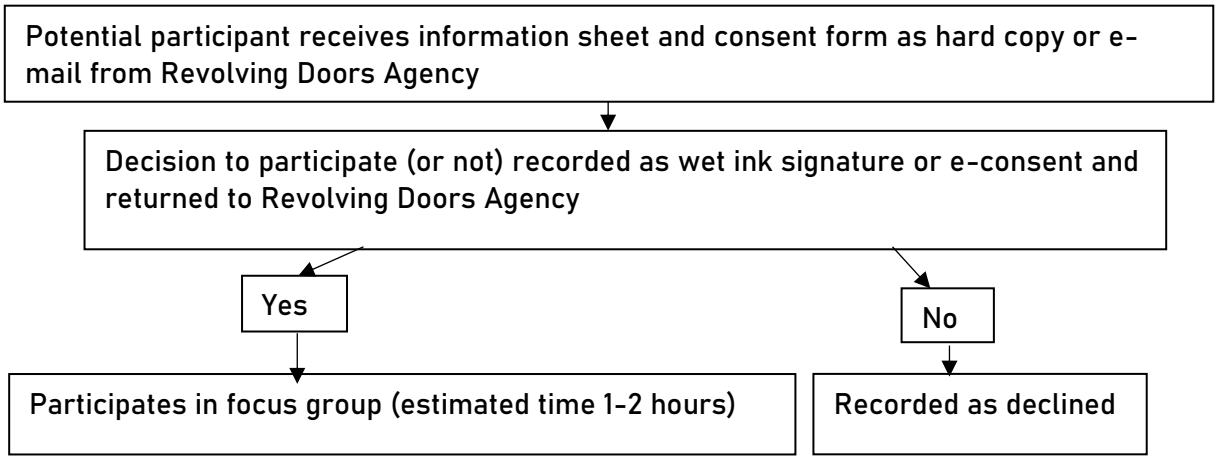


DEVELOPING QUALITY INDICATORS

1) Expert panel



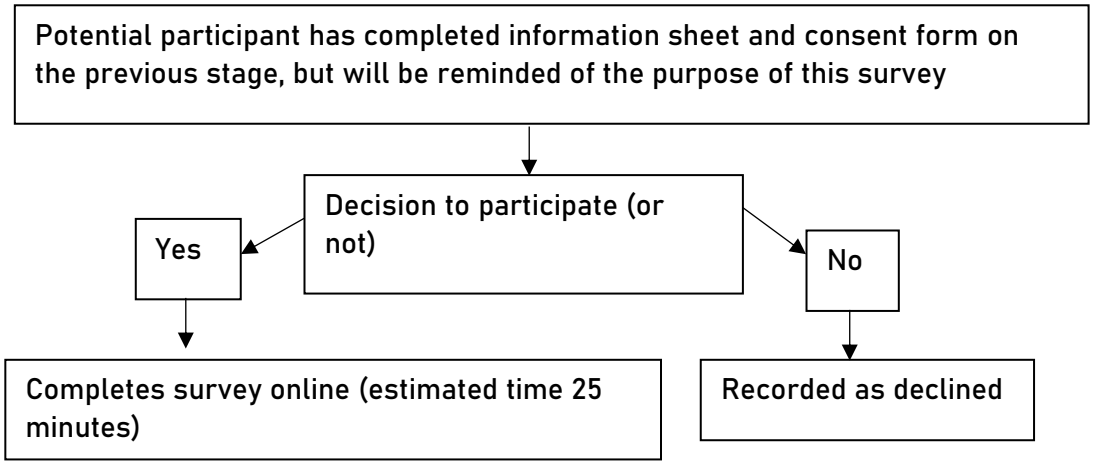
2) Service user panel



3) Systematic review of the literature – existing quality indicators identified

4) Draft set of quality indicators produced from the findings from the above stages

5) Second expert panel survey – the panel members will already have received an information sheet and consent form about this stage of the research at step 1, but will be asked to repeat consent here, following a reminder about the purpose of the survey.



6) Final discussion of quality indicators – participant will have seen information sheet and signed a consent form when completing the first expert panel survey, but will be reminded of the purpose of the discussion at the beginning of the conversation.

STUDY REGIMEN

IMPROVING DATA COLLECTION (SURVEYS OF HEATLH AND SOCIAL CARE NEEDS)

Individuals participating in this stage of the study will be asked to complete a consent form and a survey about their health and social care needs and the extent to which they are being met or to take part in a telephone/online interview (staff).

Surveys will be self-completed at probation premises, or completed over the phone or an online platform such as Microsoft Teams with answers being recorded by probation staff. They will contain questions as follows:

- Demographic data: gender, ethnicity, age, (to be used as described in the analysis below)
- Past diagnoses: Have you ever been diagnosed with: a learning disability, a learning difficulty (e.g. dyslexia), ADHD, autism, personality disorder, a mental illness? Do you have any physical or mental health conditions or illnesses lasting, or expecting to last 12 months or more?
- Service use: GP registration and use, A&E attendance
- Met and unmet needs including for social care and physical health: collected on the CANSAS-P
- Substance misuse: alcohol use (collected on AUDIT-C), drug use (collected on DAST-10)
- Mental health and suicide prevention: collected on CORE-10 and CANSAS-P

Our core focus is on recording past diagnoses, and using the CANSAS-P to identify areas of need, and if they have been met. We have also included the AUDIT-C, DAST-10 and CORE-10 as these provide additional information by indicating severity of need in key areas. This will inform probation practice (for example cut-off scores on the CORE-10 can be used to indicate a need for referral to primary [6+] or secondary care [10+]), and enable assessment of the relationship between level of need and whether or not the need has been met - providing useful data for service commissioners and providers.

Online/telephone interviews will be based on a semi-structured interview guide to ascertain feedback on what it was like to implement the survey and if/how this could be incorporated into routine practice.

DEVELOPING QUALITY INDICATORS

Individuals participating in the service user panel will be asked to complete a consent form, and to contribute to a focus group in which they will be asked to describe positive and negative experiences of accessing care, and discuss what they think probation should know about their health, what they think the characteristics of excellent care are, and how this could be measured. The focus group will either take place at an appropriate location selected by Revolving Doors or using Microsoft Teams.

Individuals participating in the expert panel will be asked to complete a consent form (provided online at the start of the surveys), and to complete two online surveys. The first survey will ask them what they think the characteristics of excellent health and social care for people on probation are, and how this could be measured (i.e. what they think good quality indicators would look like). The second survey will ask them to rate a draft set of quality indicators on a 5-point Likert scale based on whether or not they have a clear link to outcomes for service users, can be a departure point for improvement actions, and are practical to implement. They will also be asked to state if they feel that anything is missing. Finally, these individuals will participate in a discussion of the final quality indicators to inform the research team of any final changes that may be needed. This will take place at the University of Lincoln and/or via teleconference/Microsoft Teams to suit participants.

SCHEDULE OF PROCEDURES

Informed consent will be taken for each element of the study. Each element will only occur once as follows:

- Survey on health and social care needs: exact timing is dependent on the stage that probation is at on their roadmap to recovery from the pandemic, but is likely to be over a period of three months between months 3 and 9 of the overall project
- Service user panel: month 7
- Expert panel survey one: month 2
- Systematic review: months 1-8
- Expert panel survey two: months 11-12
- Final discussion of quality indicators: month 16

WITHDRAWAL

Participants can withdraw from any element of the study at any time. For all of the surveys (of service users and the expert panel), data will be collected anonymously. Therefore, participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date may not be erased in accordance with the University's Research Privacy Notice and information given in the Participant Information Sheet and may still be used in the final analysis.

ETHICAL AND REGULATORY CONSIDERATIONS

ASSESSMENT AND MANAGEMENT OF RISK

We do not anticipate that taking part in this study will cause any pain, discomfort, or changes to lifestyle for participants The burden involved will simply be the time to complete a survey/participate in a focus group (service user panel)/complete a survey and rate quality indicators (expert panel). It is possible that reflecting on health needs or past experiences around accessing healthcare may cause distress. Steps have been taken to minimise the burden by keeping the questions asked in each of these elements to a minimum and advising participants that it is up to them what they answer and how they answer – they do not need to share anything too upsetting.

The participant information sheets will make it clear that should someone discuss plans to harm their self/another, or commit a criminal offence, appropriate persons (probation staff) will be aware of this as probation staff will be directly administering the surveys, or giving them out for self-completion, and looking at the participants' answers straight afterwards. Surveys will only be administered in an appropriate space – so if conducted by phone or online (e.g. via Microsoft Teams), a participant will need to have an appropriate (private) space in which to take part.

It will be made clear to focus group participants that they do not need to discuss any past experience that they may find upsetting, and questions will be designed so that this is unlikely to occur. In the event that an individual did become upset, they will be told that they can take a break, or leave the group. All participants will receive a debrief sheet containing details of support services.

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted. Medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

ADVERSE EVENTS

Due to the nature of this study, no adverse events are anticipated and no adverse event data will be collected.

ETHICS REVIEW AND COMPLIANCE

The study shall not commence until the study protocol, information sheets and consent forms have been reviewed and approved from a Research Ethics Committee and relevant probation ethics permission is obtained

The sponsor will be responsible for deciding whether amendments are substantial and non-substantial in collaboration with the Chief Investigator.

Where an amendment is required to study documentation that required REC approval, changes will not be implemented until REC approval is received. Where an amendment requires local approval this shall be sought prior to the amendment be implemented at each site in accordance with the approval letter.

Should an amendment be required to eliminate an apparent immediate hazard to participants this may be implemented immediately and the REC and the NRC will be notified as soon as possible.

Minor amendments for logistical or administrative purposes may be implemented immediately

Amendments will be logged on the Sponsor's Study Amendment Log and stored in the Trial Master/Site File(s).

Annual Progress Reports shall be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given – until the end of the study.

A final report shall (where possible) be submitted to the REC within one year after the end of the study.

If the study is terminated prematurely the CI will notify the REC, including the reasons for premature termination.

PEER REVIEW

The proposal for this study was reviewed internally at the University of Lincoln, and in addition was reviewed by the Research Design Service, and the NIHR funding committee.

PUBLIC & PATIENT INVOLVEMENT

The need for this research was partly informed by information provided by participants in our previous research in this area. Service users and probation staff have been involved in developing and focusing our funding application for the project. They have supported the researchers in developing participant information sheets, invitation letters and consent forms and an interview schedule. The survey has been piloted with people with lived experience of the criminal justice system.

An expert panel including probation staff, and a service user panel will contribute to the development of quality indicators. Here, people with lived experience of the criminal justice system will be recruited by Revolving Doors staff and Peer Researchers. In a focus group co-facilitated by the Peer Researchers, participants will be invited to share their experiences of accessing care.

A service user and probation staff will also be part of the steering group and contribute to dissemination of findings, including producing an easy-read summary of findings, and attending sessions on writing for publication if desired.

PROTOCOL COMPLIANCE

Accidental protocol deviations may occur at any time. Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, these will require immediate action and could potentially be classified as a serious breach.

DATA PROTECTION AND PATIENT CONFIDENTIALITY

All study staff and investigators will comply with the principles of the Data Protection Act (2018) in protecting the rights of study participants with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's/Regulations core principles.

No personal data will be included in our publications - responses in all elements of the research will be anonymised (e.g. through appropriate word replacement in text during transcription of the focus group) and/or reported at aggregate level.

Individuals participating in the service user and expert panels will be asked whether they would like their name, or the name of the organisation that they are based with, to be included in acknowledgments sections of any publications/presentations from the research as appropriate. This will be part of the participant information resources.

Data will be stored on the University network, in an area of a shared drive that is only accessible to the research team, and/or on OneDrive. Hard copies of participant consent forms and surveys will be stored in locked metal filing cabinets.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Lincoln representatives, the REC, NRC and the regulatory authorities. Anonymised data may also be added to a repository at the end of the study. This will be made clear on the participant information resources.

INDEMNITY

The University of Lincoln as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance.

ACCESS TO THE FINAL DATASET

Members of the research team, including Revolving Doors Peer Researchers, will have access to the final dataset. Anonymised data will also be added to the University of Lincoln institutional repository and/or an external repository.

DISSEMINATION POLICY

The data custodian will be the Chief Investigator on behalf of the University of Lincoln.

During months 18-19, we will produce

- A report for NIHR
- An easy read summary
- Journal articles on the health and social care needs of people on probation, their patterns and experiences of service access, and the development of quality indicators.

We will make the final set of quality indicators freely available to the National Probation Service, and further disseminate them through members of the expert group, a blog site for the project, social media the Probation Institute, and the Confederation of European Probation.

The tools used within the surveys will also be available to the National Probation Service for future use.

Authorship eligibility guidelines and any intended use of professional writers

All team members will contribute to write up and dissemination. Authorship will be based on the degree and nature of involvement with different elements of the project. Those taking part in the service user and expert panels will be named, or their organisation will be named, in acknowledgements sections as appropriate if they have consented to this.

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