**Ethics Application Form**

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| **Ethics Application ID**: 844797  **Details:**   |  |  | | --- | --- | | **Risk:** |  | |  |  | | **Title:** | Stroke Audit Machine Learning (SAMueL-2) | | **Version** | 0 | | **Applicant:** | Keira Pratt-Boyden | | **Submitter:** | Keira Pratt-Boyden | | **College:** | Health and Community Sciences | | **Student Project:**  **Supervisor:**  **Module Code:** | No | | **Date Application Submitted:** | 6 Jan 2023, 14:32 | | **Project Duration:** | 1 Mar 2023 - 31 Mar 2024 | | **Funder:** | NIHR |  |  | | --- | | **Project Description:**  Our aim is to improve the ways that information from the Sentinel Stroke National Audit Programme (SNAAP) is used by physicians to inform the care that they provide, with a focus on the use of intravenous thrombolysis in acute stroke pathways. We will use machine learning (ML) to identify where and why clinically unwarranted differences in care arise, and work with stakeholders to ensure that they can access timely and useful information that enables quality improvement. The qualitative aspect of the study involves learning about physicians’ and wider stroke staffs’ views, experiences, and current practices concerning thrombolysis, ML, and SSNAP as separate but interrelated components. The things we learn from staff involved in thrombolysis will shape the design, contents, and implementation of our ML work. The three specific objectives being addressed by the qualitative aspect of this study are: 1) To generate empirically and theoretically informed knowledge about how thrombolysis is currently delivered, centered on physicians’ views, understandings, and practices. 2) To learn more about how stroke physicians’ and staff think and feel about or use SSNAP, and about the current and potential use of ML in improving clinical practice 3) To combine what we learn from objectives 1 and 2 and use this knowledge, alongside contributions from stakeholders, to develop and refine the application of ML to national audit data Our primary research question is: What should a machine-learning model based on SSNAP data look like, do, and deliver if it is to optimise improvement, and reduce unwarranted variation, in thrombolysis? |   **Project Scope:**   |  | | --- | | **Does your research involve only secondary data?**  No | | **Is your project exclusively based on published literature or library/archival materials which have been specifically curated for general public access or display?**  No | | **Does your project require external ethical review? *Please give details of the external review route for this research.***  No | | **Will your research involve human participants?**  Yes | | **Will your research involve the use of animals?**  No | | **Does this project involve the use of sensitive or restricted materials?**  No | | **Does the project have the potential to cause environmental damage or harm?**  No | | **Please summarise the background to the project?**  Introduction:Stroke is the commonest cause of severe adult disability (Feigin et al. 2014; Xu XM et al. 2018) and outcomes can be significantly improved for selected patients though the use of time-critical treatments such as thrombolysis, which dissolves blood clots (Stroke Unit Trialists Collaboration 2013; National Institute for Clinical Excellence 2019). For thrombolysis to be useful, it needs to be given as soon after the stroke as possible, but it is not appropriate for all patients and can be risky. The Sentinel Stroke National Audit Programme (SSNAP) shows that the use of thrombolysis varies hugely (ranging from 5% and 25% of patients between hospitals), even for patients with similar treatment pathways and with similar characteristics: in some hospitals it is rarely used but in others it is given to a quarter of stroke patients (Royal College of Physicians 2013). The speed of thrombolysis delivery also varies widely, with some hospitals taking an average of 90 minutes and others taking less than 30 minutes to administer the clot-busting drug. The Sentinel Stroke National Audit Programme (SSNAP, https://www.strokeaudit.org/) is a major national healthcare quality improvement programme based at King’s College London. SSNAP measures the quality and organisation of stroke care in the NHS and is the single source of stroke data in England, Wales, and Northern Ireland. SSNAP collects compressive data on all stroke admissions and publishes quarterly and yearly reports on stroke care. SSNAP measures both the processes of care (clinical audit) provided to stroke patients, as well as the structure of stroke services (organisational audit) against evidence-based standards, including the 2016 National Clinical Guideline for Stroke. The overall aim of SSNAP is to provide timely information to clinicians, commissioners, patients, and the public on how well stroke care is being delivered so it can be used as a tool to improve the quality of care that is provided to patients. The overarching aim of the SAMueL-2 project is to build state-of-the art simulation and machine learning tools that further enhance the analytical capabilities of SSNAP. ML is a type of artificial intelligence (AI) that learns patterns from historical data to predict new outcomes. Through this work we hope to build insights that may also be applied to the other 22 national audits. (https://www.hqip.org.uk/a-z-of-nca/). SAMueL-2 will investigate how a ML-based approach to informing clinical practice can be designed and adapted to suit the needs of physicians with the aim of supporting the optimal implementation of thrombolysis. The qualitative component of SAMueL-2 is central to this work and will explore how physicians at a particular hospital use thrombolysis, in order to identify how use of machine learning applied to the national stroke audit will be of greatest value in reducing variation in thrombolysis use. We will learn from current initiatives in the NHS which are aiming to reduce variation in the treatment of thrombolysis, as well as investigate physicians’ and other stroke staffs’ experiences and understandings of the use of ML in healthcare. This will help us anticipate any barriers to implementation and change in practice, as well as the current social and institutional contexts and conditions that influence this. In SAMueL-1, we found a significant proportion of uneven thrombolysis use is due to individual physician decision-making. Improving the uneven use of thrombolysis is thus likely to involve significant changes in practices and stroke pathways in hospitals, as well as requiring physicians to consider how they treat certain kinds of patient. If we are to enable this, we need to develop a comprehensive understanding of the (interconnected) processes and impacts of decision-making around thrombolysis in varying organisational and clinical contexts so we can understand how our ML model, applied to national audit data, might contribute to improving care. In the quantitative component of SAMueL-2 we will identify and explore factors that influence thrombolysis treatment using ML. Machine learning can provide us with certain types of information, such as how making specific changes might change practice: for example, from our existing work we know that if ambulances can arrive sooner at hospital, then the use of thrombolysis is likely to increase. What ML cannot do is tell us what information from the audit is most useful to physicians and managers; how to present it in the most useful way, and how to ensure that the use of ML is aligned to the implementation of meaningful improvements in care. To achieve these things, we need to use qualitative data to build a theory of change that can inform what we do and how we do it. We will use qualitative methods of data collection and analysis to study the interpersonal dynamics between staff involved in thrombolysis, the organisational capacity to innovate (both local, central hospital and NHS level), and the broader cultural context of scope for adaptation and quality improvement in hospitals currently using thrombolysis. In combination with ML data, this will maximise the clinical application of our research findings and enhance the development of ML outputs to support staff working with stroke patients to facilitate their use of the national stroke audit to reflect on their decision making around thrombolysis. This protocol refers only to the qualitative component of SAMueL-2. This protocol has been produced by qualitative researchers within the University of Exeter who undertake applied health services and implementation research, and who have specific expertise in observational methods. Theoretical Framework:Our theoretical framework is influenced by research around decision-making, implementation and behaviour change. Researchers often claim that they plan to study or influence decision-making. In fact, studies of decision-making have repeatedly found that ‘decisions’ cannot be easily traced to a single moment in time, often appear incoherent, and do not follow logical pathways (Dreyfus and Dreyfus 1987; Gladwin 1980; Johnson-Hanks 2002; Krzyworzeka 2013; Ortiz 1967). Decisions are often more complex: constructed collectively with peers or with close social relations (Sjölander-Lindqvist and Cinque 2013) and are typically made ‘outside’ (external to) the high-pressured, time-constrained spaces where decisions are actively sought (Krzyworzeka 2013) such as acute care environments. In healthcare settings, what appear to be individual clinical decisions involve collective experience and judgments situated in, and shaped by, organisational culture, organisational climate, and social context (Aarons 2012, Broom 2009, Glisson 2002). For example, when studying clinical decision-making in primary care, Gabbay and le May (2004) found that physicians decide how to deal with specific situations based on a combination of different types of types of information, including written guidelines, personal experience and historical factors, as well as ongoing conversations external to the critical care situation, with colleagues or trusted experts. From our previous work on variation in thrombolysis rates (Allen et al. 2022) we know that physicians’ perceptions of why they make decisions - and find it hard to change - are influenced by multiple practical and resource constraints as well as considerations of risk to patients. A single decision about whether to thrombolyse a patient might at first appear to involve the application of explicit rules to a known situation. In fact, the decision will involve many considerations and influences: for example, from SAMueL-1, we know physicians often think of their patients as "different" (somehow harder to treat) to the broader population, and (by implication) that standard rules of care cannot be straightforwardly applied. To enable us to understand and interpret the way in which these multiple constraints and considerations shape practice, we will use the NASSS (non-adoption, abandonment, scale-up, spread and sustainability) framework (Greenhalgh et al. 2017). Designed to help predict and evaluate the success of technological interventions or programs in healthcare, the NASSS framework is valuable in our data collection and analysis because it allows us to identify and consider the multiple, overlapping influences (or "domains") of influence on health-technology uptake, use, and sustainment. The NASSS framework works on the assumption that (any) technology (I.e. ML included) will only have an effect if it comes into connection with, and operates alongside, people, places organisations and policies (Halford 2021); specifically when technology creation is not perceived as separate from social impact. Based on our prior work from SAMueL-1, and on the literature, we know that thrombolysis rates and decisions around thrombolysis are affected by many of these seven domains which include the (health) condition itself, the technology, stakeholder perceptions (I.e., physicians' varying interpretations of the clinical situation and the attitudes of colleagues both within and outside of their unit) and broader organisational and societal factors. Taking this approach will give us scope to both inform the design of our ML model and its application to SSNAP and to plan its implementation into practice. Using NASSS to frame our findings will help us to understand these multiple intersecting layers of influence and to identify ways of addressing them. Our primary research question is: What should a machine-learning model based on SSNAP data look like, do, and deliver if it is to optimise improvement, and reduce unwarranted variation, in thrombolysis? | | **Please explain the aims of the project and what you intend to achieve**  We will answer our primary research question through three work packages (WPs): Work package 1: (objective 1) Study of context to refine our ML approach This work package will begin immediately after REC and HRA approvals. We will use semi-structured interviews and focused observations with stroke physicians and key stroke staff across at least 3 different NHS Trusts so that we can: 1) understand and learn about physicians’ current experience of the delivery of thrombolysis in order to identify how our ML findings could be applied 2) explore the institutional environment of thrombolysis in acute stroke care settings in selected UK NHS Trusts so that we can identify and address institutional, organisational and social barriers to potential change and improvement To address these aims we will explore the following three aspects of the context in which stroke care is delivered, and ask following questions: Organisational culture :How is expertise around thrombolysis produced? Who, and what, influences decision making in a particular unit? How has stroke care come to be delivered in the ways it currently is, both nationally, and in particular settings? What are its historical antecedents and organisational requirements, and how are these understood by physicians? What social and institutional relationships influence the delivery and outcomes of thrombolysis? How, when, where, why, and by whom are practices around thrombolysis enacted and transferred? What influences the way a clinical situation is interpreted? We know that different physicians may treat the same patient in different ways; how do factors, such as severity of stroke or the presence of family members, affect the decision made? How does practice reflect different ideas or expectations of illness, treatment, and recovery? Decision pathways :What happens from the initial point information about a patient is first received, patient arrival at hospital, to the decision to thrombolyse (or not?) How do staff interact throughout the stroke pathway? How does communication work between different departments and teams – who does the communicating, and how? What is communicated at transition points, such as handover from paramedics to ED or stroke-care staff? How do time (and timing) change thinking and practice about thrombolysis? We know that the time since stroke onset is relevant to physician decision-making, but less about other aspects such as dayshifts vs nightshifts, weekdays vs weekends, summer vs winter, and so on. How do the everyday challenges of working in hospital affect and change ‘ideal’ stroke pathways? Personal perspectives :What is the physician experience of delivering thrombolysis? What impacts decision-making around thrombolysis for individuals/ an organisation? How is thrombolysis understood among different individuals? What personal factors, histories and experiences influence physicians’ attitudes to thrombolysis? How do individuals think about and reflect on the differences between what they do and what others do, and between what they do and what “Evidence” says they should be doing? Are there differences between how staff report decisions and how they behave in practice – that is, between what they do and what they say they do? Who do physicians speak to when they are or have been uncertain what to do? This might be in response to new information for example (perhaps from guidelines, SSNAP, or research), in thinking about types of situation, or in reflecting on a situation in which they were unsure of how to proceed. Focussing on these three core elements and specific questions will enable us to understand the personal, social, organisational and institutional contexts around thrombolysis as a way of developing and refining our ML model. Work package 2: (objective 2) To improve our understanding of physicians’ and wider stroke care staffs’ attitudes and interpretations of information from the national stroke audit, SSNAP, and to the use of ML, to inform reflection on use of thrombolysis. WP2 will begin shortly after WP1 and run concurrently. Semi-structured interviews and focused observation will centre on the following questions: What are the human and technological processes by which we get AI (ML) adopted into a national audit? How do physicians/stroke staff feel about receiving the kind of information the audit can provide through ML? (i.e. are there particular sensitivities around this information? – especially given the recent pandemic, stress levels among staff, and many hospitals’ rates declining?) As our project is particularly focussed on how to use stroke audit (SSNAP) data, we will also ask questions around the general acceptability and understanding of SSNAP among individuals, such as the following; What are physicians' relationship with the audit? Are physicians aware of SSNAP data? How do they interact with the SSNAP data (I.e. online?) How are SSNAP data discussed in their work? What do they think of the data? What might they need in order for this information to be useful to them in day-to-day practice? These questions will help us learn how physicians think about and use SSNAP (or not), which will provide us with fundamental context for WP3: testing our ML findings which are based on SSNAP data. Work package 3: (objective 3) ML testing and learning in order to understand the feasibility and potential usefulness of ML In WP3, we will use the findings from the quantitative component of SAMueL-2 (ML based on SSNAP) and explore how these can be used to encourage reflection around decision-making regarding thrombolysis. We will iteratively test ML findings in 3 co-production workshops, complemented by the data from semi-structured interviews and observation. Co-productive workshops will reveal some of the ways in which people, including physicians, interpret and make sense of information relating to their practice; they will reveal both individual and social components to decision making and how multi-professional interactions influence decisions regarding thrombolysis (Greenhalgh 2010; Tsoukas and Vladimirou 2001). Both co-production workshops and interviews will include staff involved in wider stroke care, such as commissioners, managers and planners, to include broader organisational understandings. A good of example of ‘testing findings’ occurred in our preparatory work: in a stakeholder engagement workshop, a group of physicians were asked whether they would thrombolyse a patient who was disabled prior to having a stroke. Clinical guidance says regardless of disability, patients should be treated the same - however- many physicians said they would not give thrombolysis to an already-disabled patient. In the workshop, we asked physicians why they might not thrombolyse a patient with a pre-existing disability and answers revealed they had uncertainties around the ‘risk-benefit’ calculations to patients. In other words, physicians were anxious to ‘add’ to, or somehow worsen, the disability levels and therefore quality of life of already disabled patients. This finding has enabled us to include 'disability level' as a factor in developing our machine learning tool to support physician decision-making. We anticipate that we will need at least three co-production workshops to explore our ML findings, with the content of each shaped by what we have learned up to that point. Workshops may involve visual props to facilitate or initiate discussion with physicians, such as slides or animations presenting our findings or showing SSNAP data. Participants will be identified either from the three NHS Trusts in which we will already have undertaken our observational work, or from interviews (which include staff across Trusts). Overall objectives:Qualitative research will be conducted with an overall objective to determine physician perspectives and concerns towards the use of machine learning and stroke audit. The interviews will review and explore the conduct of clinical practice in thrombolysis. This will also help highlight what factors are important in communicating the ML model results. Qualitative methods will be used to: Explore current understanding, practice and rationale for the use of thrombolysis for ischaemic stroke, in order to establish reasons for the variance in the use and speed of thrombolysis. Elicit physician perspectives on machine learning feedback, and stroke audit, to understand how our results are best presented in a way that is useful and likely to have an impact on their practice. Identify potential routes for the implementation of machine learning feedback, to inform and improve future stroke management. Explore stroke pathways to identify key areas that any one hospital needs to focus on, in order to provide potential feedback and optimise their thrombolysis use. Outcomes:The outcomes of our qualitative study will be: 1) WP1 a detailed understanding of how thrombolysis works in given settings; as well as 2) WP2 attitudes towards and understandings of ML and SSNAP data in this context, and 3) WP3 ML refinement. Outputs from the qualitative aspect of SAMueL-2 will be a systematic and comprehensive analysis using the NASSS framework, which will feed into how we aim to use ML and national audit data to support clinical decision-making around thrombolysis. Our outcomes 1) 2) & 3) will highlight possible integral mechanisms as well as human and contextual factors relevant for specific patient populations, while making recommendations on some of the likely conditions for successful implementation of ML in the national stroke audit. Along with our analysis, these production outputs will feed into qualitative research journal articles and a project report. | | **Has the project been peer reviewed?**  Yes | | **Please describe the peer review process and outcome**  This protocol is based on the SAMueL-2 grant application submitted to NIHR (NIHR134326) which was peer reviewed as part of the funding award process by the NIHR Funding panel. This qualitative research protocol has additionally been reviewed by the team's PPCI group (verbally and via email- as was appropriate for members), and by two internal experienced senior qualitative researchers based at the University of Exeter. We have formally addressed internal reviewers Drs Conny Guell and Rosemary Simmonds' key comments below. PPIC comments were integrated throughout. | | **Please explain why your project has not been peer-reviewed** | | **Please describe how the research will be conducted in a way that ensures its quality and integrity**  The study protocol has been developed by Dr Keira Pratt-Boyden (a qualitative health researcher) Dr Julia Frost (qualitative expert) and Dr Iain Lang (Health Science Implementation expert), as advised by a senior Medical Sociologist, Prof Cathy Pope. Patient and Carer Involvement (PCI) an external advisory board, and health care professional stakeholders have also contributed to the design of the study, participant information sheets, consent forms and the topic guides. The SAMueL-2 Study study has been funded by an NIHR Grant and underwent peer review as part of that process. In addition, we have sought internal peer review (independent to the study) as part of preparing this ethics application and addressed their recommendations. We will report the research using the relevant reporting guidelines, such as COREQ, as well as report a summary of the findings back to participants. The research will be conducted following ethical principles and good clinical practice guidelines. At all stages of this work, we adhere to the British Sociological Association Statement of Ethical Practice 2017 and the Digital Research Ethics Annexe. The research team are experienced in conducting this type of research and the work will be overseen by the wider SAMueL-2 qualitative advisory and external advisory groups. |   **Research Methodology:**  **Please provide a summary of the research methodology using the table below. For each method, please describe how it has been selected and how the data will be analysed.**   |  |  |  |  | | --- | --- | --- | --- | | **Method** | **Description of Participants** | **Why method was selected** | **Data Analysis** | | Qualitative semi-structured interviews (face-to-face, phone or online) | For all our methods, we will recruit NHS stroke physicians and stroke staff from NHS trusts (across secondary and tertiary care) who are involved in thrombolysis. These may be: Consultant stroke physicians, Registrars (all levels), stroke and ED nurses, stroke service managers (clinical and non-clinical) and commissioners. We will also seek to recruit physicians working alongside the ISDNs and COP, as well as physicians from hospital sites outside of the 3 selected for clinical observation in order to maximise the applicability and variation of our sample. We will identify staff located across rural and urban areas, with different professional roles, grades and experience. Up to 20 NHS stroke care professionals will be recruited for semi-structured interviews. | The sample of up to 20 staff will be interviewed as ‘key informants’ representative of different positions in stroke care delivery or management at the chosen NHS Trust sites. Interviews will enrich the observational data: by capturing the diversity of perspectives, experiences and beliefs of physicians around thrombolysis, SSNAP and ML; and exploration of a significant range of issues in thrombolysis practice.For physicians, the interviews will offer a space outside of treatment contexts where we can explore their perceptions of thrombolysis and its impact in a more structured way, and discuss relevant factors related to other attitudes toward audit data and ML or AI more broadly. For healthcare professionals involved in governance, interviews will explore their personal experiences of thrombolysis improvement initiatives, including of technology, audit and ML. Where relevant to the experience of individuals, topics will also include organisational history and characteristics, and professional roles and relationships. | Qualitative data analysis will take a pragmatic analytical approach, drawing primarily from the nonadoption, abandonment, scale-up, spread and sustainability (NASSS) framework (Greenhalgh et al. 2017)Designed to help predict and evaluate the success of technological interventions or programs in healthcare, NASSS is valuable in our data collection and analysis because it allows us to identify and consider the multiple, overlapping influences (or "domains") of influence on health-technology uptake, use, and sustainment. The NASSS framework works on the assumption that (any) technology (I.e. ML included) will only have an effect if it comes into connection with, and operates alongside, people, places organisations and policies (Halford 2021); when technology creation is not seen as separate from social impact. Based on our prior work from SAMueL-1, and on the literature, we know that thrombolysis rates and decisions around thrombolysis are affected by many of these seven domains which include the (health) condition, the technology, stakeholder perceptions (I.e., physicians' varying interpretations of the clinical situation and the attitudes of colleagues both within and outside of their unit) and broader organisational and societal factors. Taking this approach will give us scope to both inform the design of our ML model and its application to SNAAP and to plan its implementation into practice. Using NASSS to frame our findings will help us to understand these multiple intersecting layers of influence and to identify ways of addressing them.All data collected and produced from observations, workshops and interviews will be used to build an integrated dataset that seeks to triangulate and combine the learning from the different data and by synthesising the qualitative and quantitative data. | | Focussed Observation (face-to-face or online) | The core sampling frame for hospital observation will be 3 NHS Trust sites with low thrombolysing rates; The Royal Sussex County hospital (University Hospitals Sussex Foundation Trust) in Brighton, The Royal Cornwall hospital (Foundation Trust) in Truro, and The Diana Princess of Wales hospital (Northern Lincolnshire and Goole Foundation Trust) in Grimsby. The researcher will spend up to two weeks at each site, at times that permit observation of stroke-care at different points (evenings, weekends, etc.) as well as core times when stroke units hold review meetings.It is not possible to give a precise figure, such as a sample size, for focused observation. The observation element of our research does not aim for a specific number of participants and our approach instead involves purposive sampling, as outlined below. It is anticipated that KPB will engage with various stroke care staff over the course of the 9 months research period, in which the WPs 1, 2, and 3 data collection will be collected. The exact number of hospital stroke pathways observed will depend on how many patients present with symptoms associated with acute stroke during the observation period. On average, there are 100, 000 patients admitted to hospital with acute stroke each year in the UK (NICE 2021), and of these, 11% receive thrombolysis (the national target set out by the 2019 NHS long term plan is 20%). Different units (depending on size and geographic location) will receive different quantities of patients to thrombolyse or not; lower thrombolysing units thrombolyse on average one patient a week; whereas larger and higher thrombolysing units could be thrombolysing one a day. COP and ISND meetings take place approximately bi-monthly, and stroke review meetings vary between sites, but many review thrombolysis cases once a month – and SNAAP data quarterly. | Observation allows us to observe different physicians’ approaches to decision-making around thrombolysis, to identify the conditions for change in NHS stroke care, and to generate a real-time capacity for institutional learning.Research in SAMueL-1 identified that the NHS Trust Research & Development (R&D) departments in low-thrombolysing sites (often in smaller, more rural and socio-economically deprived parts of the country) have limited capacity to participate in qualitative studies. Our experience also shows that accessing NHS Trusts that meet our demographic objectives, and recruiting staff with capacity to participate in interview studies, is very time-consuming (particularly in terms of physician time). We aim to involve such sites as they are under-represented and under-served in research, and are the key targets of intervention; therefore we have tailored our methods to mitigate the challenges of such sites. A research delivery manager from the Southwest Peninsula Clinical Research Network (CRN) and NHS consultant stroke physician have advised that observation places less burden on physicians than interviews, not least because it means physicians will not have to leave their clinical activities. We will not ask physicians to do anything they would not already be doing within the hospital setting, so the presence of a researcher will not change treatment or practice. This is the same in the case of observation of online meetings (described below). We have also been advised by a group of 5 stroke physicians (located in the Southwest of the UK) in a stakeholder engagement workshop, that they are “used to being observed” and that from their perspective, observation "would not be a problem”. Further, conversations with NHS England (NHSE) and other stakeholders (the Integrated Stroke Delivery Networks, ISDNs, also described below) have emphasised the highly sensitive nature of research around thrombolysis, particularly for low-thrombolysing units. Many lower thrombolysing units feel scrutinised. The longitudinal nature of observation will allow the researcher appropriate length of time in each hospital, which will be essential to building rapport and trust and mitigating any concerns physicians might have (for example, that taking part in our research might mean their performance is being judged). It will also allow us time to document the different shift patterns, rotations, and timings of the hospital setting (such as weekends and nights). This will allow for the analysis of stroke pathways and thrombolysis decisions as they unfold in different contexts.The main focus of observation will be physicians and other staff involved in stroke care (with a focus on thrombolysis) including stroke nurses, registrars, service managers, clinical directors, nurses, stroke consultants, ED staff, geriatric registrars, among others. The principle researcher, KPB, will have an honorary contract at each observation site and will observe meetings and processes related to stroke/thrombolysis both at the sites and online. Online observation of meetings will include the new COP and ISDN networks. | The researcher KPB will keep detailed records of the range of activities which she observes informed by a team-generated observational protocol (Tai, Fischer and Noble 2021) (attached). The observational protocol identifies lines of enquiry using the NASSS framework (as above). KPB will also have regular supervision with other qualitative team members to inform and review the protocol. | | Co-production workshops (face-to-face) | Up to 24 participants will take part in the co-production workshops – of which there will be up to 3.Participants will be identified using the same criteria as observational or interview participants: i.e. physicians and other staff involved in stroke care (with a focus on thrombolysis) including stroke nurses, registrars, service managers, clinical directors, nurses, stroke consultants, ED staff, geriatric registrars, among others. | We will undertake up to three co-production workshops with physicians engaged in stroke care. These will enable us respond to our third aim: to co-produce ML output in a way that maximizes its acceptability and, ultimately, its use in bringing about improvements in clinical practice. Our workshops will be focussed on the ML findings from the wider SAMueL-2 project and will take place as and when ML findings arise. | The workshop data will be analysed and triangulated in the same way as observational and interview data; primarily using the NASSS framework and drawing from other health implementation literatures, both inductive and deductively. |  |  | | --- | | **Where will the project be undertaken?**  The key study settings for WPS 1, 2, and 3 will be 3 different NHS hospitals and online. Observation and some interviews will be undertaken in 3 separate NHS Trust hospitals across England; The Royal Sussex County Hospital in Brighton, The Royal Cornwall Hospital in Truro, and The Diana, Princess of Wales Hospital in Grimsby, in key areas where staff conduct thrombolysis. These sites have been chosen as they are all low thrombolysing units; their thrombolysis rates were 9,7,5,4 (Brighton) 8.9, 8.6, 6.5 (Truro) and 5, 5, 5, 7 (Grimsby) in the last SSNAP audit. Additionally, The Royal Cornwall and The Diana are located in areas which been identified as having high poverty rates and poor health outcomes (Northeast Lincolnshire is counted amongst the top 10% most deprived neighbourhoods in the UK) (Ministry of Housing, Communities & Local Government, 2019). Both hospitals are rated as ‘needing improvement’ by the CQC. The Royal Sussex is rated as ‘outstanding’, and is in a relatively affluent part of the UK (Brighton), but still struggles with low thrombolysis rates, which makes for an interesting and diverse sample. The key areas of observation within these hospitals are where stroke pathways take place. These vary between hospitals, and will be different (tailored to) each hospital, but can include: ED departments and Stroke Units among others. The addresses of the 3 sites are: Royal Sussex County Hospital, Eastern Road, Brighton, BN2 5BE, NHS University Hospitals Sussex, NHS Foundation Trust Royal Cornwall Hospital Treliske, Truro, Cornwall, TR1 3LJ, Royal Cornwall Hospital Trust Diana, Princess of Wales Hospital, Scartho Road, Grimsby, North East Lincolnshire, DN33 2BA, North Lincolnshire and Goole NHS Trust Co-production workshops will also be held at the three selected hospital sites, in rooms chosen as appropriate by staff, or online. The rooms will be selected on the basis of accessibility to participating stakeholders- accounting for quiet, privacy and access to the necessary technology. Other settings will include online remote technology (MS Teams or Zoom) to collect interview and observational data from other NHS professionals across Wales and England. The researcher will undertake online observations/interviews on University premises in a private room, windows closed. If University premises are not available (e.g., due to a Covid lockdown) the researcher may conduct online interviews at home, in a private, enclosed room, windows closed. | | **Please describe details of any permissions required to use the location(s) specified**  We will require the consent of the participant to undertake in observation, interview or co-production workshops.We have initial agreement from the three named NHS Trust sites - and will be supported by the Clinical Research Network (CRN) to obtain full agreement upon approval. On receipt of HRA/REC approval, we will seek local site approval through the NHS Capacity & Capability procedures via the HRA Approval process. | | **Will the research involve International travel and/or travel to a potentially risky environment?**  No | | **Please describe the risk to researchers** | | **Please provide details of the actions to be taken to reduce risks to researchers and procedures to deal with potential problems** | | **Will the research involve the use of hazardous or controlled substances?**  No | | **Please describe the risk to researchers** | | **Please provide details of the actions to be taken to reduce risks to researchers and procedures to deal with potential problems** | | **Does the research have potential to cause distress or discomfort to any member of the research team?**  Yes | | **Please describe the risk to researchers**  Observation in particular parts of hospital (throughout the stroke pathway) will include some potential risk, particularly in areas of intense activity such as ED (Emergency) departments. | | **Please provide details of the actions to be taken to reduce risks to researchers and procedures to deal with potential problems.**  The hospital sites will be responsible for KPB’s safety whilst she is conducting observation, and will fill out site specific risk assessments prior to the observational visit (see Risk Assessment and Management Strategy and Policy v9.2 (cornwall.nhs.uk) for an example). The researcher has done specific trainings on researching in difficult settings, and has experience conducting research in other potentially volatile settings, such as a mental health ward. She will also be compliant with HRA processes for ED research and local Trust processes. During observation, the researcher will operate a ‘buddy system’ with her line manager JF and another member of the qualitative team IL, and will text JF/IL before commencing and after ending a shift at a hospital. They will have details of her fieldwork schedule, including transport and accommodation. If JF/IL do not hear from KPB after the agreed time, JF/IL will contact the hospital security team - who KPB will identify and notify before commencing observation there. She will debrief with the qualitative team (JF, IL) weekly, and CP if and when needed.KPB will be staying in accommodation as close to the hospital as possible to minimise travel risks. Travel contingency and worker safety plans are in place with the University of Exeter Health and Safety Officer. If the researcher finds the research distressing, she can contact the University wellbeing services at any time 24/7 at: Spectrum Life | Colleague Wellbeing | University of Exeter. | | **Does the research involve lone working?**  No | | **Please describe the risk to researchers** | | **Please provide details of the actions to be taken to reduce risks to researchers and procedures to deal with potential problems** | | **Does the research involve visiting participants in their home or other non-public space?**  No | | **Please describe the risk to researchers** | | **Please provide details of the actions to be taken to reduce risks to researchers and procedures to deal with potential problems** | | **Please describe the training which will provided to researchers in relation to the risks identified above**  Good Clinical Practice (GCP) and Research Integrity training have been undertaken by the researcher. | | **Does the research involve the use of genetically modified organisms?**  No | | **Please describe the use of GMOs in the research** |   **Human Participants:**   |  | | --- | | **Identifying participants**  We will recruit NHS stroke physicians and stroke staff using purposive sampling (Palinkas et al. 2015; Bernard 2018) The purposive sampling framework will entail: staff from NHS trusts (across secondary and tertiary care) who are involved in thrombolysis. These may be: Consultant stroke physicians, Registrars (all levels), stroke and ED nurses, stroke service managers (clinical and non-clinical) and commissioners. We are also guided by the concept of ‘information power’: the idea that a sample that holds more information, and is more relevant for the study, will require fewer participants (Malterud et al. 2016). We will also seek to recruit physicians working alongside the International Stroke Delivery Networks (ISDNs) and Communities of Practice (COPs), as well as physicians from hospital sites outside of the 3 selected for clinical observation in order to maximise the applicability and variation of our sample. We will identify staff located across rural and urban areas, with different professional roles, grades and experience. | | **Please list any inclusion criteria to be used**  Participants will be included if they are: Currently employed by the NHS (secondary or tertiary care) in a role as specified in the purposive sampling frame described below and will have; Professional knowledge and/or experience of the emergency stroke pathways. Will be aged 18 years or over. | | **Please list any exclusion criteria to be used**  Participants will be excluded if they: Have no knowledge or experience of thrombolysis. Are under 18 years. | | **Please specify if you are using any of the protected characteristics as defined in the Equality Act 2010 as an exclusion criteria**  We will not be excluding those with protected characteristics. We will be recruiting people older than 18 as they will not have appropriate professional experience before then. For example, all physicians must have undertaken further education and further specialist training before becoming a stroke physician or indeed being involved in thrombolysis (at any level). | | **Please specify how potential participants, records or samples will be identified and by whom**  Physicians will be recruited into the research via our local CRN contact, or via the principle researcher KPB. Contacts with various NHS Trusts have already been made through existing and new networks (i.e. Integrated Stroke Delivery Networks, Communities of Practice, and stroke consultants) via initial conversations regarding capacity and interest. CRN/the researcher will send out the Participant Information Sheet and Expression of Interest Form to the selected participants. The Information Sheet will ask potential participants to return the Expression of Interest to the research team directly, e.g. either by email or in a postage paid envelope if returning a paper copy. If there is no response to the invite within 14 days, they will call the participant to confirm that they have received the information and determine level of interest. If they are unable to make contact with a participant within 20 days of the letter, those participant details will be deleted from the SAMueL-2 study records and another participant with similar sampling characteristics sought from the datasets already provided. Similarly, details of sampled participants who do not wish to take part in the study, will be removed from the SAMueL-2 study’s records and another participant with similar sampling variables will be sought for inclusion in another wave of recruitment. Recruitment will be ongoing throughout the study. Following confirmation of the receipt of the Expression of Interest Form, potential participants who have responded positively will be contacted by phone. This phone call will be used to check that the potential participant has received and understood the information provided, to answer any questions they may have about the study, checking whether any arrangements are required to improve ability to engage with the study, and to arrange a date for an interview. Recognising that not all people may have access to the necessary technology, or have time to be involved in an interview, we want to specifically offer to conduct observation with those who may struggle to be involved in research, to ensure we reach as diverse a population as possible (including those aforenamed hospitals who have been identified as having low thrombolysis rates, and two are in socioeconomically deprived parts of the UK). Where possible, participants will be asked to return their signed consent form by email emphasising that the participant may withdraw their consent at any time. Where this is not possible, consent will be recorded verbally during the initial telephone call providing time for questions before reading out the consent statements and receiving a verbal response from the participant. Consent will be checked again, by asking participants if they are still happy with the answers they previously provided and whether any questions/concerns had arisen, at the beginning of the interview. Once target recruitment numbers of up to 20 interviews, or 24 co-production workshop attendees have been achieved, all unrecruited participants details will be deleted from the SAMueL-2 study data set. | | **Does your research involve participants who are in a potentially vulnerable situation?**  No | | **Please describe why the participants may be in a potentially vulnerable situation** | | **Please describe how the participants will be protected** | | **Approaching participants**  Physicians identified as eligible for the qualitative interviews and observation through portfolio adoption by the Clinical Research Network will be contacted by research nurses from their local NIHR CRN Stroke Network. The contact email to eligible physicians will include a study recruitment form (consent to be contacted sheet). On receipt of this information the qualitative researchers will consult the sampling frame and contact eligible physicians to be interviewed. Invitations to the co-production workshop will be extended to physicians who have been involved in observations, interviewed for the study or expressed an interest in the study, and people in managerial positions in services providing the stroke pathway. Initial expressions of interest may be through the CRN or KPB. The purpose of the coproduction workshop is to maximise the range of feedback and capturing of differing perspectives related to ML and SSNAP. | | **If applicable, describe any existing relationship between the investigator(s) and participant(s) (e.g. teacher-student or employer-employee). Please explain how this will be managed to reduce the risk to participants**  The Research Fellow conducting the interviews has no prior relationship to any of the participants taking part in this research. | | **Recruiting participants**  Participant Information sheets will be provided to potential participants and posters will be shown during observation to act as a reminder to participants (see attached documents). | | **Please describe how long you will allow participants to decide whether to take part**  For interviews and co-production workshops, participants will have between 48 hours and up to 4 weeks to take part. This is because of the long duration of the research period (March-December 2024) which has allowed for maximum flexibility and contingency. For observation, the researcher will give as much notice as possible. Participants will at least 48 hours to decide if they wish to participate. | | **Will informed consent be obtained from the research participants?**  ***Please describe the process that will be used to obtain and record valid consent. Remember to upload copies of any consent forms to the application.***  YesAll participants will be required to give informed consent prior to taking part in the interview or co-production workshop. Where written consent is not possible verbal consent will be utlised. At the beginning of each interview, or workshop, the consent form will be read out and to ensure participation confirmation each participant will be asked if they are happy to participate and to provide verbal consent. The PI will sign the consent form indicating verbal consent has been provided. Also, participant agreement to audio recording meeting will be obtained. For all interviews and co-production workshops, the participant will be provided with a PIS that includes a written explanation of the workshop or interview, its purpose, process, and how the data will be stored and used.For observation, after NHS Trusts’ personnel have agreed to take part in the observational study, the initial method of informed consent for individual staff during observation will be verbal; partly to minimise time burdens for busy NHS professionals and for practical reasons as the research will be ‘on the go’ (see verbal observation script in attached documents) . Asking professionals to sign written consent forms on the job defeats the purpose of using a non-intrusive research method (c.f. US-PEX study, NIHR Grant Reference Number 14/156/06) and allows flexibility for those hospitals which struggle to be part of research. At the start of each observation, after a brief reminder of the purpose of the research, including the plan to record consent, each participant will be asked to state verbally that they provide consent to taking part. The researcher will record responses on an encrypted audio recording device. They have the option to sign written consent forms if they wish. Not all individuals on the hospital premises will be deemed to be research “participants” and it is not possible or feasible to gain consent from each individual observed. The researcher will not collect identifying data from these individuals, and all staff will be informed of the research via an introductory email, and the poster, which will be placed around the hospital. We believe that most participants will find this method of consent during observation acceptable and convenient based on initial conversations with physician stakeholders and our CRN partners. The PIS for observation (which KPB will hand out prior to the commencement of observation) will also include information about this consent plan such that participants are informed in advance. Details will also state that if preferred, a separate individual conversation about the study can be held and a written consent form completed. During online meetings, the observation poster will be shown, and participants will have the option to express consent verbally, with a clear visual signal, or by private-messaging KPB using teams/zoom. They will also have the option to email her, or the CI. Further considerations:We follow the British Psychological Society code of ethics which stipulates that observational research is acceptable in public situations “where those observed would expect to be observed by strangers” (The British Psychological Society Code of Human Research Ethics, 2010, p25). During focussed clinical observation, the researcher will put up a poster around stroke units, E D department, and any other relevant areas identified in consultation with the CRN and stroke consultants. The poster will explain that a researcher will be present (the same poster will be shown at the beginning of COP and ISDN meetings and consent taken before meetings begin.) The poster will explain the research focus is not on patients, but stroke care professionals and how they are conducting their work. The professional with responsibility for the patient (I.e. lead physician) will also be briefed about how to communicate the presence of a researcher to the patient. The patient will be asked by the healthcare professional whether they agree to the presence of a researcher observing their work, or not. If they do not agree, the researcher will step out the room and discontinue all observations regarding that patients’ treatment. Our PCI group has been consulted about if the patient is unable to communicate and the majority agreed that if information (PIS) was clear that the focus was staff, not patients, they would have themselves (theoretically) consented. One member commented however that he lacked capacity during his time in stroke care and would not have wanted a researcher present. If the patient lacks capacity (as identified by the healthcare professional) the researcher will remove themselves from the ED until this episode of treatment has been completed. For interviews and the coproduction workshop, the researcher will explain that the informant may view, censor, or withdraw the audio transcripts at any point before transcripts will be anonymised. Interviews and workshops will be audio recorded and transcribed as per above mentioned processes. | | **How will feedback be provided to participants either during or at the end of the project?**  Results (including anonymised data) will be disseminated via academic publications, conferences, meetings with stakeholders (I.e. stroke physicians and NHS management professionals) Updates, news, outcomes, information on the study in general and study progress is available throughout the period of study and afterward via https://samuel-book.github.io/samuel-1. | | **Withdrawal of participation**  **Please describe the arrangements that will be made for participants to withdraw their participation and data (either in part or in full) both during and after the research project**  The consent procedure will emphasize participants’ rights to withdraw from the study at any time. During observation, the participants can ask the researcher to leave the room at any point, or email her or the CI to opt out of the study. The researcher will no longer observe any activities undertaken or collect or store information about the withdrawn participant. It will be explained that withdrawing consent will not have any effect on the participant or their professional activities. No names will be written into observational notes (codes i.e. 'A2') will be used, and data will be further anonymised after it has been collected, which means taking out any personal identifying information. There will be a week or two between us collecting the data and anonymising it, when people can withdraw their consent for this information. After the data has been anonymised, we will no longer be able to withdraw it, since we will not be able to identify who the data came from.For interviews and the coproduction workshop, the researcher will explain that the informant may withdraw or leave the interview/workshop at any time, without question. The participant may also view, censor, or withdraw the audio transcripts at any point before transcripts will be anonymised. | | **Please explain any consequences for the participant of withdrawing from the study and indicate what will be done with the participant's data if they withdraw**  To allow participants to withdraw from the study, we will hold a linking code between data and personal information but this will be kept separately from any other study information. This is only for the purpose of deleting data should anyone want to withdraw participation. Participants will be informed in advance of the interviews, observation or workshops about their rights of access to study information and that after anonymisation, when the data has been analysed and quotes extracted from individuals, it may not be possible to fully withdraw all data from all study outputs. De-anonymised data will be securely deleted (i.e. paper shredded or deleted from all files). | | **Please describe whether and how participants will be able to withdraw their data after the results have been published**  It may not be possible for participants to withdraw from the study after results have been published. | | **Will the research involve actively deceiving participants? *Please describe the nature of the deception and how any associated risks will be mitigated.***  No | | **Does the project involve study or participation in social media activity? *How will social media sites be used?***  No | | **Will the research involve discussion or collection of information on potentially sensitive, embarrassing or distressing topics?*****Please provide more information about the sensitive topics involved.***  YesThere is a chance participants may find it distressing to discuss how they treat their patients. If the participant becomes distressed during interview, they will be advised to contact their local employer and signposted to the relevant support organisations. Physicians are likely to have established ways of dealing with distress due to working with stroke patients (daily life and death situations) in their daily practice and have support within their team to do so. The information sheet about the interview will emphasise that people can pause or terminate the interview at any time, without having to provide a reason. | | **Does the research involve investigation or possible disclosure of illegal activities or behaviours? *Please describe the potential illegal activities or behaviours involved. Describe the potential nature and risk of disclosure, how participants will be informed of the potential disclosure and how the risks will be mitigated.***  No | | **Is it possible that this research will lead to awareness or the disclosure of actual or intended harm to a participant or other individual?** ***Please describe the procedures to be followed by members of the research team in the event of disclosure, including any training to be provided for researchers before the research starts and information to be provided to participants***  No | | **Is there a risk of physical harm, psychological harm or discomfort for participants, or prolonged or repetitive testing which may be a burden to participants?**  No | | **Please describe each potential risk and the likelihood of the risk occurring** | | **Please describe how each potential risk will be monitored and mitigated** | | **Does the research involve invasive or potentially intrusive procedures?**  No |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Procedure** | **Description of Participants** | **Location** | **Number of occasions Estimated Completion Time** | **Frequency and Duration** | **Researcher(s) carrying out procedure** |  |  | | --- | | **Does the research involve the administration of substances?**  No |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Substance and Method of Administration** | **Description of Participants** | **Location** | **Number of occasions Estimated Completion Time** | **Frequency and Duration** | **Researcher(s) administering substance** |  |  | | --- | | **Will your research involve collecting, storing or processing human tissue samples?**  No | | **What types of human tissue samples are involved?** | | **Please describe how each type of sample will be a) Collected b) Processed and c) Stored** | | **Please describe what will happen to the samples at the end of the study, including how they will be destroyed, transferred or retained** | | **Please advise the latest sample storage end-date.** | | **If the samples are to be retained for use in your future research or by other researchers, please describe the process that will be followed to store the samples and to provide access to them at a later date** | | **Does your research require you to have a DBS check?**  No | | **Will the participants receive financial compensation or other rewards?**  Yes | | **Please describe the financial compensation or other rewards**  Participants involved in the co-production workshops will be eligible to receive a £40 voucher, or may opt to donate the £40 to the charitable organisation- medicins sans frontiers - in acknowledgment of their time and contribution. This has been agreed with the funder. | | **Please describe how you will deal with compensation if participants choose to withdraw**  The £40 will be donated to medicins sans frontiers |   **Animals:**   |  | | --- | | **Does your research involve live animals?** |  |  |  |  | | --- | --- | --- | | **Species** | **Number** | **Life Stage** |  |  | | --- | | **How many live animals will be used?** | | **How and where will the animals be sourced?** | | **Indicate if the source is within the UK, within EU/EEA, or in the rest of world** | | **Please include information on how and where you will obtain the animals, including any suppliers involved and how you are assured that the suppliers are meeting appropriate welfare standards** | | **Are wild animals involved?** | | **Indicate where these are obtained, if they are captured for this project and if so, how they are captured** | | **Please explain how each capture method is the most refined for the species and purpose of the study. Include details on the positioning of traps, frequency of checking and the potential for non-target species to be captured** | | **How will you examine and assess any animals that are found to be ill or injured at the time of capture?** | | **How will you ensure the competence of the person responsible for making this assessment?** | | **If sick or injured animals are to be treated, how will you transport them for treatment?** | | **If sick or injured animals are to be humanely killed, which methods will you use?** | | **If animals are to be transported, please describe how, by whom and how welfare standards will be maintained during transport (e.g. environmental conditions, frequency of checking)** | | **Does your research involve tissues obtained from animals?** | | **What type of samples?** | | **How many samples?** | | **How and where will the samples be sourced? Please describe the sources of the animal tissue. Describe any permissions and transfer agreements which may be required** | | **Please indicate if the source is within the UK, within EU/EEA, or in the rest of world** | | **Please include information on how and where you will obtain the tissue samples, including details of any suppliers involved and how you are assured that the suppliers meet appropriate animal welfare standards** | | **If tissue samples are to be transported, please describe how and by whom. Describe how the sample integrity will be maintained** | | **Explain why you need to use animals and/or animal tissue in this project** | | **Explain how you have considered the principles of the 3Rs (Replacement, Reduction, Refinement)** | | **Replacement:** | | **Reduction:** | | **Refinement:** | | **Does your project involve observation without intervention? *Please describe the observations.*** | | **Does your project involve any interventions or invasive procedures? *Please describe the interventions or invasive procedures.*** | | **Is the research regulated under the Animals Scientific Procedures Act 1986 (ASPA)?** | | **Is the animal research to be conducted outside the UK?** | | **Would the research be regulated under the Animals (Scientific Procedures) Act 1986 as if it were to be conducted in the UK?** | | **Does this research require another licence or site permissions for conducting the research or for transporting animals or samples? *Please describe the license or site permissions required.*** | | **What arrangements are in place to protect the welfare of the animals concerned** | | **Describe any potential harms or adverse effects that will be experienced by the animals** | | **Describe how the potential harms and adverse effects will be monitored and mitigated** | | **How long will the animals be kept?** | | **What will happen to the animals at the end of the research?** | | **What training will be provided for the research team?** |   **Security:**   |  | | --- | | **Describe the use of sensitive or restricted materials** | | **Please describe any associated risks and how they will be mitigated** |   **Environmental Impact:**   |  | | --- | | **Describe the potential environmental impact of the research or its results** | | **Please describe how any potential impacts will be monitored and minimised** |   **Data Management:**   |  | | --- | | **What data will be collected and used during the project?**  We will collect personal information, observation, workshop and Interview data. The data will be managed in line with five principles of data protection stipulated by the UK General Data Protection Regulation (UK GDPR, http://www.exeter.ac.uk/gdpr/principles/) and Data Protection Act (DPA) 2018). The researchers will follow specific guidelines on managing data issued by the University of Exeter (http://www.exeter.ac.uk/ig/dataprotection/guidance/). Personal information: Personal contact details of participants will not be shared with anyone outside of the KPB and the CRN representative, who will comply with the requirements of the General Data Protection Regulation 2018 and the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles. The personal information that will be kept are participants’ contact details and consent forms. Participant names and work contact details will be held during the study to make arrangements for interviews/workshops and/or share findings at the end of the study. Personal contact details will only be kept if participants give direct permission and consent for this. These data will be stored securely on SharePoint and accessed by our CRN contact and KPB only, separately to workshop/interview transcripts/audio files. Emails from participants about taking part/logistical arrangements will be deleted as soon as no-longer needed. The personal information will be kept on a password protected electronic encrypted file in the study computer folder, on the Exeter University’s SAMueL-2 study Sharepoint site. All personal information will be stored separately from all participant anonymised data in line with GDPR guidelines. We will hold no paper copies of personal information. All personal information will be deleted after the study’s completion unless otherwise agreed with consent from the participants. Electronic versions of the consent form will be completed remotely and stored electronically and in a different folder to the participant data. Where hard copies of the consent form are completed, they will be scanned and stored electronically. Interview data: Audio-files will be transcribed, prior to being uploaded into NVivo. A transcriber we have been recommended (employed via the University of Exeter Temp Bank) will access the audio files in the encrypted Sharepoint folder and will upload the transcripts to the same folder. Once checked by the researcher, all audio files will be deleted. All data will be depersonalised and any identifying information replaced by an unrelated sequence of characters. To allow participants to withdraw from the study, we will hold a linking code between data and personal information but this will be kept separately from any other study information. This is only for the purpose of deleting data should anyone want to withdraw participation. Participants will be informed in advance of the interviews about their rights of access to study information and that after anonymisation, when the data has been analysed and quotes extracted from individual interviews, it may not be possible to fully withdraw all data from all study outputs. Data will be maintained in a secure and password protected encrypted computer folder on the Exeter University Sharepoint. The linking code will be kept in a different folder on a different, encrypted computer and filed in a password protected folder, only identifiable by key members of the research team. Any written consent forms will be scanned and stored electronically on university encrypted and password protected systems and computers, and the paper versions then securely destroyed. Audio recordings will be collected using encrypted and password-protected university devices and transferred to SharePoint at the earliest opportunity. Recorded files from workshops/interviews will be transcribed by an external transcribing company which complies with the GDPR. We will have a contract from the University of Exeter Legal Services department to ensure that we have the required agreement in place between the transcription service and us. Participant identifiers will be anonymised during transcription. A number and a job role will be allocated for each participant. Job roles will be grouped into generic job roles shared by other participants to avoid identification of individuals. The numbers/job role will also be used as ‘speech identifiers’ in transcripts of the workshop discussions. Any audio/video recording which may contain personal identifiers will be securely destroyed as soon as results have been published. Any hand-written observational notes will be written up immediately electronically by KPB and stored in SharePoint and the paper notes will be securely destroyed as soon as possible. All transcriptions will be kept on SharePoint and destroyed after publication of project outputs. The Chief Investigator will be responsible for overseeing the management of the research data throughout the project but he will not have access to the qualitative data. The day-today management of the qualitative data will be solely the responsibility of KPB, as advised by JF & IL. KPB, IL and JF will be responsible for quality control, audit and analysis of data, reporting any problems to chief investigator Dr Michael Allen and the Sponsor. | | **Is there an access control process or a gatekeeper for access to data e.g secondary data? *Please describe the access control or gatekeeper processes that you will need to follow.***  No | | **Where and how will data be stored during the project?**  See as above. Data will be securely stored on Sharepoint. No hard copies will be stored (they will be scanned and uploaded onto SharePoint then securely destroyed). | | **How long will the data be retained after the project is complete?**  31 Mar 2034 | | **Will any of the data be used in future research and/or made available to other research projects?**  Full transcripts will not be shared in their entirety to protect the anonymity of participants. However, requests for excerpts of the data will be considered on an individual basis, with options for interested parties to contact the Chief investigator or publication corresponding authors. | | **How will data be destroyed when it is no longer needed?**  Any hard copies of eg consent forms will be uploaded to Sharepoint and disposed of using confidential waste bins.Following the completion of transcription, the audio recordings will be destroyed immediately. Personal data will be destroyed in line with consent (either when people withdraw from the study or when the study has ended). | | **How will access to the data be controlled?**  During the study, access to the anonymised data will be restricted to members of the qualitative SAMueL-2 study research team involved in analysis, Prof Cathy Pope, Drs Julia Frost, Iain Lang and Keira Pratt-Boyden, and the named transcriber employed via the university Temp Bank, via encrypted and password protected files on Sharepoint. Personal data will only be accessible to the researcher involved in data collection and the CRN. | | **Will your project involve processing confidential data belonging to organisations? *Please explain the strategy you will deploy if the organisation wishes to remain anonymous.***  No | | **Will your project involve collecting new personal data from participants? *Please describe what types of data will be collected, and for each type, describe how it will be collected.***  YesObservational data will be collected from the principle researcher using coded notes (i.e. no names of participants), onto an encrypted, password protected tablet, then uploaded onto the University's SharePoint and further anonymised (i.e. other potential identifiers removed). | | **Does the research involve photographs, videos or audio recordings of research participants? *Please describe and explain how you will ensure that you are only capturing data from research participants who have given consent to participate in the research project.***  YesAt the beginning of each interview, and the co-production workshop, if a consent form has not been returned via email or post, the consent form will be read out and to ensure participation confirmation each participant will be asked if they are happy to participate and to give a verbal consent. Participant agreement to record the interview or workshop will be obtained. At the end of the interview or workshop, the audiorecording will be stopped.No data will be captured or recorded from research participants who have not given their consent during observation. | | **Will participant data be treated as confidential? *Please describe the procedures to be used to ensure confidentiality of data both during the conduct of the research and in the release of its findings.***  YesThe personal information that will be kept by the research team are participants’ contact details and consent forms. Personal contact details will only be kept if participants give direct permission and consent for this. The personal information will be kept on a password protected electronic encrypted file in the study computer folder, on the Exeter University’s secure server. All personal information will be stored separately from all participant anonymised data in line with GDPR guidelines. We will hold no paper copies of personal information. All personal information will be deleted after the study’s completion unless otherwise agreed with consent from the participants. | | **Will participant data be anonymous? *Please describe the procedures to be used to ensure anonymity of participants both during the conduct of the research and in the release of its findings. If you propose to anonymise data, please explain the strategy you will use here.***  YesAudio-files will be accessible to a named University of Exeter employed transcriber via SharePoint. Transcripts will be securely returned to SharePoint and uploaded directly into NVivo. All data will be depersonalised and any identifying information replaced by an unrelated sequence of characters. To allow participants to withdraw from the study, we will hold a linking code between data and personal information but this will be kept separately from any other study information. This is only for the purpose of deleting data should anyone want to withdraw participation. Participants will be informed in advance of the interviews, workshops or observation about their rights of access to study information and that after anonymisation, when the data has been analysed and quotes extracted from individual interviews, observations or workshops, it may not be possible to fully withdraw all data from all study outputs. | | **Will participant data be pseudonymised or link-anonymised? *Please explain the arrangements for managing the process including, but not limited to, the length of time that the link will be retained, who will have access to the linking information and how the linking information will be stored.***  YesAs above: All data will be depersonalised and any identifying information replaced by an unrelated sequence of characters. To allow participants to withdraw from the study, we will hold a linking code between data and personal information but this will be kept separately from any other study information. | |