Qualitative Protocol

This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY
Stroke Audit Machine Learning

SHORT STUDY TITLE / ACRONYM

SAMueL-2

PROTOCOL VERSION NUMBER AND DATE

Version 1.0 05.01.2023

RESEARCH REFERENCE NUMBERS

IRAS Number:	322303
SPONSORS Number:	2021-22-40
FUNDERS Number:	NIHR134326

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.

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.

For and on behalf of the Study Sponsor:

Signature:

.....

Date:
...../...../.....

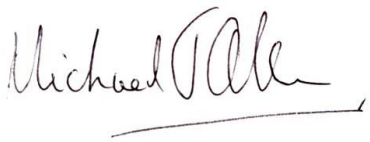
Name (please print):

Pam Baxter

Position: Research Governance Manager (Health and Social Care)

Chief Investigator:

Signature:



Date:

15/12/2022

Name: (please print):

Michael Allen

LIST of CONTENTS

GENERAL INFORMATION	**Page No.**
HRA PROTOCOL COMPLIANCE DECLARATION	i
TITLE PAGE	ii
RESEARCH REFERENCE NUMBERS	ii
SIGNATURE PAGE	iii
LIST OF CONTENTS	iv
KEY STUDY CONTACTS	v
STUDY SUMMARY	v
FUNDING	vi
ROLE OF SPONSOR AND FUNDER	vi
ROLES & RESPONSIBILITIES OF STUDY STEERING GROUPS AND INDIVIDUALS	vi
STUDY FLOW CHART	vii
SECTION	
1. BACKGROUND	1
2. RATIONALE	
3. THEORETICAL FRAMEWORK	
4. RESEARCH QUESTION/AIM(S)	
5. STUDY DESIGN/METHODS	
6. STUDY SETTING	
7. SAMPLE AND RECRUITMENT	
8. ETHICAL AND REGULATORY COMPLIANCE	
9. DISSEMINATION POLICY	
10. REFERENCES	
11. APPENDICES	

KEY STUDY CONTACTS

Chief Investigator	*Dr Michael Allen* (MA) Senior Research Fellow Address: PenARC, Institute of Health Research, College of Medicine and Health, St Luke's Campus, University of Exeter, Exeter, Devon, EX1 2LU Tel: +44 (0) 1392 726080 Email: m.allen@Exeter.ac.uk
Joint Chief Investigator	*Professor Martin James* Consultant Stroke Physician Department of Medicine, Royal Devon and Exeter NHS Foundation Trust/University of Exeter Medical School Phone: 01392 406070 Email: martinjames@nhs.net
Sponsor	University of Exeter Sponsor Representative *Ms Pam Baxter* (PB) Senior Research Governance Officer Research Ethics and Governance Office University of Exeter, Lafrowda House St Germans Road, Exeter EX4 6LT Phone: 01392 72 3588 Email: p.r.baxter2@exeter.ac.uk
Funder	*Mr Martin Simpson-Scott* Research Manager (Monitoring) National Institute for Health Research Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) at NIHR, University of Southampton Alpha House, Enterprise Road Southampton SO16 7NS Email: martin.simpson-scott@nihr.ac.uk
Qualitative Research Leads & Key Protocol Contributors	*Dr Keira Pratt-Boyden* (KPB) Research Fellow Institute for Health Research University of Exeter College of Medicine and Health St Luke's Campus, Exeter EX1 2LU Phone: 01392 722970 Email: k.z.pratt-boyden@exeter.ac.uk *Dr Julia Frost* (JF) Senior Lecturer Health Services Research Institute for Health Research University of Exeter College of Medicine and Health St Luke's Campus, Exeter EX1 2LU Phone: 01392 722970 Email: j.frost@exeter.ac.uk *Dr Iain Lang* (IL) Senior Lecturer Public Health Institute for Health Research University of Exeter College of Medicine and Health St Luke's Campus, Exeter EX1 2LU Phone: 01392 76087

	Email: l.lang@exeter.ac.uk
Qualitative research advisory group:	*Professor Ken Stein* (KS) Professor Public Health Institute for Health Research University of Exeter College of Medicine and Health St Luke's Campus, Exeter EX1 2LU Phone: 01392 726067 Email: ken.stein@exeter.ac.uk *Mr Leon Farmer* (LF) Lead Patient representative l.farmer@exeter.ac.uk and Patient and Carer Involvement (PCI) group: X 6 members (Supported by PCI Research Assistant Laurene Asare l.asare@exeter.ac.uk) *Professor Martin James* (MJ) (Contact details as above) Professor Catherine Pope (CP) Professor of Medical Sociology Medical Sociology and Health Experiences Research Group, Nuffield Department of Primary Care Health Sciences, Medical Sciences, University of Oxford catherine.pope@phc.ox.ac.uk
External Advisory Group:	*Dr Ajay Bhalla (AB) (chair)* Consultant Stroke Physician and Lead Clinician at Guy's and St Thomas' Hospital. Associate Clinical Director, Sentinel Stroke National Audit Programme. ajay.bhalla@gstt.nhs.uk *Professor Gary Ford (GF)* Professor Stroke Medicine Oxford Academic Health Science Network Magdalen Centre 1 Robert Robinson Avenue Oxford OX4 4GA gary.ford@ouh.nhs.uk *Professor Martin Utley (MU)* Professor of Operational Research, Clinical Operational Research Unit, Dept of Mathematics Faculty of Maths & Physical Sciences

	University College London **m.utley@ucl.ac.uk**

STUDY SUMMARY

Study Title	Stroke Audit Machine Learning
Internal ref. no. (or short title)	SAMueL-2* **Note: This is a follow-on project to a NIHR HS&DR project (Ref: 17/99/89), referred to here as SAMueL-1.* *https://samuel-book.github.io/samuel-1*
Study Design	Qualitative research (focused observation, co-production workshops and semi-structured interviews)
Study Participants	Staff involved in NHS stroke care; primarily stroke physicians; registrars, stroke nurses, geriatricians and ED workers within NHS Trusts. Staff involved in stroke services; commissioners, managers, quality improvement and support staff.
Planned Size of Sample (if applicable)	Semi-structured interviews: up to 20 participants Observation: Approximately 2 weeks of observations at each stroke unit (x3) Co-production workshops: up to 24 participants
Planned Study Period	The qualitative study described in this protocol are part of a NIHR SAMueL-2 (NIHR134326) which runs from 01 April 2022 to 31 March 2024.
Research Question/Aim(s)	Our aim in SAMueL-2 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 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?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research Health Services and Delivery Research (HS&DR) programme (NIHR) Martin Simpson-Scott (contact details as above)	£588,745

ROLE OF STUDY SPONSOR AND FUNDER

Role of Sponsor

The University of Exeter is the sponsor of this study. As employees at the University of Exeter the named researchers on this study are contractually bound to adhere to the University's ethical policies and governance structures.

The study sponsor will ensure that the research team has access to resources and support to deliver the research as proposed and that responsibilities for management, monitoring and reporting of the research are in place prior to the study commencing. The sponsor will ensure that there is agreement on recording, reporting and reviewing significant developments as the research proceeds and approve any modifications to design, obtaining requisite regulatory authority.

The sponsor will assume responsibility for operating the management and monitoring systems of the research.

Prior to the study commencing the sponsor will be satisfied that:

- The research will respect the dignity, rights, safety and well-being of participants and the relationship with healthcare professionals.
- Where appropriate the research has been reviewed and approved by an NHS Research Ethics Committee and/or the Health Research Authority Approval Programme.
- The Chief Investigator, and other key researchers have the requisite expertise and have access needed to conduct the research successfully.
- The arrangements and resources proposed for the research will allow the collection of high quality, accurate data and the systems and resources will allow appropriate data analysis and data protection.
- Organisations and individuals involved in the research agree the division of responsibilities between them.
- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted to significant developments during the study, whether in relation to the safety of individuals or scientific direction.
- There are arrangements for the conclusion of the study including appropriate plans for the dissemination of findings.

The sponsor plays no role in the design of this study, and will have no role in data analysis or interpretation, or writing up of findings of the study.

Work will be submitted to the funder (NIHR) for publication in Health Services and Delivery Research (ISSN: 2050-4537). For any other publications we will alert NIHR prior to publication (after acceptance of publication).

Role of the Funder

The research funder has the responsibility to ensure that there is a proper use of the funds they control. The study is funded by the NIHR HS&DR stream. The Funder has reviewed the programme/study plan of the research and established that the research is worthwhile, of high scientific quality and represents good value for money. The research funder has assessed the experience and expertise of the Chief Investigator, other key researchers on the programme and has deemed that there is appropriate infrastructure for the research to be carried out.

The funding review process provided feedback on the design of the programme/study plan. The funder plays no further role in the design of this individual study and will have no role in data analysis or interpretation, or writing up of findings of the study. The funder will be sent all outputs prior to dissemination, but has no role in the decision to submit for publication.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

- Qualitative Research Advisory Group

Members: KS, MJ, CP, Sponsor or sponsor representative.

Frequency: Three-monthly meetings, with intermittent ad-hoc meetings if necessary and deemed so by study progress and activities.

Aim: To ensure study progress with regards to the qualitative research.

- External Advisory Group

Members: GF, AB, MU, (MA)

Frequency: Three-four meetings over two years

Aim: To provide researchers with advice on how to address any problems or challenges that might emerge throughout the lifetime of the study, and to advice on the implications of the research findings for dissemination and impact work.

- Patient & Carer Involvement (PCI) Group

Members: People who have experienced a stroke and people caring for someone after a stroke

Frequency: Four meetings over two years

Aim: To work with the qualitative researchers, reviewing the research design and documentation. To help analyse the findings and be part of the discussion on how the decision-making tool might take patients' views on risk/benefit into account.

PROTOCOL CONTRIBUTORS

Keira Pratt-Boyden has produced this protocol. Senior researchers on this study, Iain Lang and Julia Frost, have provided qualitative expertise to the design and review of the protocol, which was based on the funding application and the project plan; which received contributions and reviews from the whole study team, led by Michael Allen.

Catherine Pope has reviewed and provided comment on this protocol, and contributed to the main documents on which the study is based.

Dr Michael Allen as Chief Investigator leads the study and has reviewed and approved this qualitative protocol.

This protocol has been reviewed by two internal peer reviewers and members of the PCI group.

KEY WORDS: Stroke; Clinical Audit; SSNAP; Machine Learning; Thrombolysis; Qualitative Research; Health Services Research

Qualitative Study Gantt Chart

2023 - 2024 (Months)	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**
PCI meetings/ feedback (monthly)															
Project external advisory group (6-monthly)															
Qual steering group (3-monthly)															
Approvals (& amendments)															
Recruitment															
Data collection (interviews, observation & analysis)															

Analysis & reporting															
Report findings dissemination & publication writing															
Data archiving															

.

STUDY PROTOCOL

Stroke Audit Machine Learning

1 BACKGROUND AND RATIONALE

Stroke is the commonest cause of severe adult disability (Feigin VL, 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, https://www.strokeaudit.org/) 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 drug.

The Sentinel Stroke National Audit Programme (SSNAP) is a major national healthcare quality improvement programme based in the School of Life Course and Population Sciences 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.

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 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 types 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 and 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 is 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.

2 THEORETICAL FRAMEWORK

Our theoretical framework is influenced by research around decision-making, implementation and behaviour change. Researchers often say 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 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).

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 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 discussion with colleagues or trusted experts (2004).

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, 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 could not 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, 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.

3 RESEARCH QUESTION/AIM(S)

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? We will answer this question through three work packages (WPs):

Work package 1: Study of context to refine our ML approach (objective 1)

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 in at least 3 different NHS Trusts so that we can:

- understand and learn about physicians' current experience of the delivery of thrombolysis in order to identify how our ML findings could be applied
- explore the institutional environment of thrombolysis in acute stroke care settings in selected NHS Trusts so that we can identify and address institutional, organisational and social barriers to 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? 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 observable 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 important, but less about other aspects such as dayshift vs nightshift, weekdays vs weekends, summer vs winter, and so on.
    - How do the everyday challenges of working in hospital affect and change 'ideal' 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 (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 elements and specific questions will enable us to understand the personal, social and institutional contexts around thrombolysis as a way of developing and refining our model.

Work package 2: (objective 2) To improve our understanding of physicians' and 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 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 acceptability and understanding of SSNAP, 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: ML testing and learning in order to understand the feasibility and usefulness of ML (objective 3)

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).

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 already disabled when they had a stroke. Clinical guidance says patients should be treated the same, whatever their prior level of disability, but 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 uncertainties around ‘risk-benefit’ calculations to patients. Physicians were concerned to ‘add’ to the disability levels of already disabled patients.

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).

4 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:

1) 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.

2) 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.
3) Identify potential routes for the implementation of machine learning feedback, to inform and improve future stroke management.
4) Explore stroke pathways to identify key areas that any one hospital needs to focus on, in order to optimise their thrombolysis use.

4.1 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.

We will produce 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. **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.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

This section will (1) outline the **study design** (the methods to be used in WPs 1, 2, & 3) and how we developed it; (2) describe the core **data collection methods**; (3) explain how we will **analyse our data**. At all stages of this work, we will adhere to the British Sociological Association Statement of Ethical Practice 2017 and the Digital Research Ethics Annexe.

5.1 Focussed Observation (WP1&2)

Focused observation with healthcare professionals both in hospitals, and online, will be our primary means of data collection, for both methodological (Cubellis et al 2021) and practical (Weston et al. 2022) purposes. 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 in order to answer our key question: *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?*

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 (description below);

In-person (hospital) focussed observation will include stroke pathways (i.e., key steps and activities involved in stroke treatment); stroke-team meetings including clinical governance and case review meetings, relationship-building with specific staff in order to facilitate interviews; and occasional interaction with other staff across the Trusts (time and place according to their own schedules). Physicians will be recruited into the research via CRNs or through pre-existing networks. Contacts with various NHS Trusts have already been made through via initial conversations regarding capacity and interest.

Dr Salim Elyas (Consultant Stroke Physician and Stroke Speciality Lead, Royal Devon University Healthcare NHS Foundation Trust) has emphasised that observation of more than one site is crucial to help inform and formulate the best future model; as stroke practice and pathways vary across different hospitals and centres. 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. This will allow observation of a wide range of activities around thrombolysis, including decisions about thrombolysing as well as decisions *not* to thrombolyse.

We will complement our observation of clinical practice with online observations of relevant meetings that take place in the new NHSE Communities of Practice (COPs) (intended to improve stroke care

across hospitals) and in the Integrated Stroke Delivery Networks (ISDNs). ISDNs include providers and commissioners of services across the whole stroke pathway: they are responsible for designing and delivering optimal stroke pathways, and improving specialist stroke care, from pre-hospital, through to early supported discharge, community specialist stroke-skilled rehabilitation and life after stroke. Their development is key to delivering on the NHS Long Term Plan commitments for stroke (https://www.england.nhs.uk/ourwork/clinical-policy/stroke/). The COP platform is another initiative involving some ISDNs- which aims to connect teams, organisations and other stakeholders across the healthcare system. The new, developing stroke-related COP aims to improve communication and knowledge sharing around thrombolysis in particular among NHS and other healthcare professionals. The COP is an important platform to engage with the social learning and participation related to thrombolysis optimisation. As Egan and Jaye highlight, “communities of practice provide a structure to understand how meanings, knowledge, and skills are diffused through membership and identity and how participation and progression within communities enables access to legitimate authority or power over particular situations” (Egan and Jaye, 2009; 120). We have existing contacts within each of these improvement-oriented COP and ISDN networks, and have in-principle agreement from each to conduct online observational work with them. By observing such quality improvement initiatives, we will broaden our understanding of the influences on changes in practice, as the NASSS framework (below) suggests. Engaging with decision-makers at different levels of the system will also give us insight into how ML might be applied in other areas of healthcare.

Patients and other staff in the relevant hospital departments, as well as stakeholders involved in the COP/ISDNs, will be informed of the presence of a researcher via posters placed around the hospital or at the start of online meetings (researcher and CI contact details included as well as GDPR). Staff will also be provided with a PIS, and will be briefly introduced to KPB and will have ongoing opportunities to ask questions and contact her. Staff will be able to explain the project briefly to patients. We will not collect any data from, or about, individual patients. The researcher will not record any data about patients. If she is privy to other sensitive and/or personal information (I.e. staff talking about patients or observing a stroke pathway involving a patient), she will not record or disclose this information to anyone.

The researcher will keep detailed records of the range of activities which she observes (via handwritten fieldnotes or an encrypted, GDPR compliant, password protected tablet) informed by a team-generated observational protocol (Tai, Fischer and Noble 2021). KPB will identify lines of enquiry using the NASS framework (outlined below). KPB may also use her professional training and judgement to inform and guide observation. She will also have regular supervision with other qualitative team members to inform and review the protocol.

Hospital conditions permitting (I.e. Covid-19) some observation (for example, of review meetings) may be undertaken online as deemed necessary by particular hospitals, through whichever channel the NHS Trust and sponsor permits (such as by Teams, Zoom, or telephone). 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. The researcher has experience of conducting online observation, which can be an effective way to observe body language

(I.e., engagement/non engagement with meeting content), team dynamics and decision-making, among other things (c.f. Lyons, Tunaker and Pratt-Boyden 2022).

A method practical for our means and the various pressures surrounding the NHS, focused observation will shed light on possible human and contextual factors (social and institutional relationships) that influence the practice and effects of thrombolysis. Documenting the sociocultural and organisational influences on thrombolysis in real-time will make it possible to distinguish those factors contingent on a given locality, client population, physician group and health service (Ajjawi et al. 2020). This will enable us to provide crucial input for ML by identifying key levers for national implementation. In particular, the data gathered through observation will allow us to formulate recommendations on how thrombolysis can be optimised in a way that is tailored to the diverse needs of different patients, physicians, and organisations.

5.2 Semi-structured Interviews (WP 1 & 2)

The observational aspect of the qualitative study will be complemented by interviews. Cognisant of the aforementioned burden of interviews on staff time, we aim to interview up to 20 staff (depending on availability) either during the observational period (at their place of work), or online. Interviews will be very flexible; staff may be interviewed in any location or timeframe they choose. All interviews will be scheduled for a time and place that best suits the interviewees (hospital premises or online). This places less time pressure on staff and reduces the likelihood of issues related to lack of capability and capacity. The final number of semi-structured interviews will be contingent upon potential changes to configurations of stroke delivery such as the new ISDN currently being implemented, and in the process of forming around stroke care. Interviewing participants in ISDNs and COPs will allow us to gain multi-stakeholder and higher-level perspectives on the configuration of stroke care and thrombolysis more broadly.

Semi-structured interviews will take 30-60 minutes and in will explore physicians' and stroke care staffs' personal experiences of and perspectives on thrombolysis, views on improving practice, ML and understandings of how their practice is informed by national audit data.

While remaining flexible to project developments (such as the incorporation of new ML findings and quantitative outputs), interviews will focus on two areas:

1) differences in clinical decision-making around thrombolysis, and
2) responses to ML and audit data
3) During interviews, we may also ask physicians for their responses to findings from the ML component of this project.

The sample of up to 20 staff will be interviewed as 'key informants' representative of different positions in stroke care delivery 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. We will tailor interviews to the individuals being interviewed. For physicians, the interviews will offer a space outside of treatment contexts which 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 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. Informed by our theoretical framework, analysis will occur alongside interviewing; this will allow us to identify important concepts and the relationships between them, in line with the NASSS framework, and by synthesising the qualitative and quantitative data.

5.3 Co-production workshops:

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. Participants will be offered an optional £40 voucher for each attendance at a workshop as an acknowledgement and thank-you for their contribution and time. The £40 can also be nominated by the participant as a charitable contribution to *Medicins Sans Frontiers*.

5.4 Data Analysis

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. Interviews and coproduction workshops will be recorded. All recordings will be transcribed by a GDPR-compliant external transcriber in an anonymised format. KPB will 'sufficiently anonymise' the data using the following formula; I.e., Specialist Registrar, post Stroke Rotation, Site A, initially, then for publication Dr A, Site A. NVivo qualitative software package will be used to manage the data. Transcripts of the interviews and co-production groups, along with any outputs created by the co-production groups or physicians themselves (such as pathway maps), will be analysed and summarised thematically. All data will be kept and stored for the duration of the project in the University of Exeter's SharePoint to which KPB will have access.

Qualitative data analysis will take a pragmatic analytical approach, drawing primarily from the nonadoption, abandonment, scale-up, spread and sustainability (NASSS) framework as described in section 2 of this document (Greenhalgh et al. 2017).

6 STUDY SETTING

The key study settings for WPS 1, 2, and 3 will be NHS hospitals (3 different sites) and online. Observation and some interviews will be undertaken in 3 separate NHS Trusts 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. Publicly available SSNAP data (https://www.strokeaudit.org/results) has enabled us to identify the extent of thrombolysis use across hospitals, and therefore identify sites of particular interest to the qualitative research (centres with high or low use of thrombolysis). These sites have been chosen as they are all

low thrombolysing (I.e. under 10%) 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. These sites have different stroke pathways to one another (for example, in Cornwall, thrombolysis is delivered by E D physicians instead of stroke physicians). 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. For the purposes of this study, these three sites were chosen for the opportunity to examine the implementation of stroke improvement initiatives in diverse environments, particularly the low thrombolysing sites, which will have specific challenges different to those of the nationally higher thrombolysing sites such as the John Radcliffe in Oxford, or The Royal Berkshire (who have also provisionally agreed to take part in interviews). Including hospitals which are struggling and under-represented in research is an important part of improving diversity and inclusion within health research. As one of the NIHR strategies is to aim to serve communities where the burden of need is greatest (NIHR 2022); within this project, we aim to develop our research capacity beyond those 'tried and trusted' sites (such as in Oxford). We hope that building observational research with low thrombolysing hospitals will be part of creating a long-term relationship with those hospitals. The range of sites provides opportunity to explore the way ML might be adapted to the needs of different kinds of hospitals, so as to be offered in a manner and in settings accessible and acceptable to a range of units and populations. Co-production workshops will also be held at the three selected hospital sites, or online. The rooms will be selected on the basis of accessibility to participating stakeholders.

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 working in ambulance services, emergency departments, acute stroke units/services, ISDNs and other organisations that have a strategic overview and commissioning responsibility for stroke services in the NHS.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility (inclusion/exclusion) Criteria

7.1.1 Inclusion criteria

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.

7.1.2 Exclusion criteria

Participants will be excluded if they:

- Have no knowledge or experience of thrombolysis.

7.2 Sampling

7.2.1 Size of sample

WP1: 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.

WP2: Up to 20 NHS stroke care professionals will be recruited for semi-structured interviews.

WP3: Up to 24 participants will take part in the co-production workshops – of which there will be up to 3.

7.2.2 Sampling technique

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 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.

7.3 Recruitment

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). 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.

7.3.1 Sample identification

For all WPs, potential participants will be initially identified by (i) SAMueL-2 team members' existing contacts at NHS Trusts who have already agreed to host SAMuel-2 research activities, (ii) CRN with the objective of including a diversity of NHS Trusts across the UK. A recruitment invitation has been prepared by KPB and will be distributed via the CRN to initial contacts. Interested potential participants will be asked to respond to the email, either directly to the qualitative researchers whose details will be provided within the invitation, or to the initial contact at the CRN, who will forward the positive response onto the qualitative team.

KPB or the CRN representative will provide information to potential participants about the study via a Participant Information Sheet (PIS) and suggest potential dates/times for the first planned interview or observation. Individuals will be asked to reply to confirm willingness to participate and agree times and/or meeting arrangements. If there has been no reply after 2 weeks, there will be two follow up contacts.

Further participants may be identified during observation by KPB or other staff involved in thrombolysis (also referred to as the snowball technique).

7.3.2 Consent

After NHS Trusts' personnel have agreed to take part in 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'. 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) 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.

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 they will be informed of the research via the poster.

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 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.

A similar approach to consent will be used for any individual interviews: at the start of each interview, after a brief reminder of the purpose including the plan to record, transcribe and analysis, the recording will be started and the participant will be asked to state verbally that they consent to taking part, unless the participant requests to complete a written consent form.

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 emailing or private-messaging KPB using teams/zoom.

For all co-production workshops, the participant will be provided with a PIS that includes a written explanation of the workshop, its purpose, process, and how the data will be stored and used. The workshops will be recorded. Written consent will be sought in this instance; partly because participants are being given a £40 to acknowledge their time and the workshops are likely to be less flexible than interviews/observation due to scheduling multiple participants.

8 ETHICAL AND REGULATORY 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 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.

8.1 Assessment and management of risk

These studies will involve minimal risk to participants and some minimal risk to the researcher. For the researcher, observation in particular parts of hospital (throughout the stroke pathway) will include some risk, particularly in areas of intense activity such as ED departments. 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 (HRA 2020) 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. The hospital sites will be responsible for KPB's safety whilst on shift, and will fill out site specific risk assessments prior to the observational visit (Royal Cornwall Hospitals NHS Trust. 2022.). 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.

The main risk concerning participants is the time required from members of staff, particularly during the possibility of a pandemic 'flare up' or winter bed crisis. To minimise the time commitment required, observation will be the primary method of data collection. KPB will also offer flexible options for interview (such as during physicians' breaks). If KPB is unable to visit a study site in person (for example, due to lockdown restrictions or hospitals moving into OPEL 4) there will be the option to conduct interviews on-line.

To ensure confidentiality during online interviews, the researcher will always occupy a private room either in an appropriate university space or her home with windows and doors closed. Participants will be asked to find a quiet and private location of their choice which has access to the necessary technology. If the participant is in a location where they can be overheard the researchers will establish if they feel comfortable with this, before commencing the interview. 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 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.

Participants involved in the workshops will be asked not to discuss individual patients or cases in a way that will identify them. They will also be asked not to discuss personal identifying information about patients or professionals *outside* of the workshops. Regarding researcher risks, the qualitative team will follow the appropriate Covid 19 guidelines set out by the University of Exeter (2022) to minimise the risk of infection to themselves, their colleagues and the broader community.

On receipt of HRA approval, we will seek local site approval through the NHS Capacity & Capability procedures via the HRA Approval process. All risk management will comply with relevant Trust procedures (I.e. for Cornwall, Sussex and Lincolnshire) (see Royal Cornwall Hospitals NHS Trust. 2022 for an example). All study supporting information will be compliant with the General Data Protection Regulations (the GDPR 2018) and the Data Protection Act 2018.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

University of Exeter Medical School (UEMS) REC, Health Research Authority (HRA) review and participating NHS Trust approvals will be sought prior to the start of recruitment and data collection. The study will be governed in line with the University CMH REC, HRA and NHS Trust approval requirements. In particular, the Chief Investigator MA will provide reports as required and notify the appropriate approval body of the end of the study and submit a final report with the results, including any publications/abstracts. All correspondence with the approval bodies will be retained. Appropriate progress reports and final reports will also be provided to the study Sponsor. As discussed above, informed consent to participate in each study will be obtained from the participants.

Before any site can enrol participants into the study, the Chief Investigator's or designees will ensure that appropriate approvals from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator's designees, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designees will work with sites (R&D departments at NHS sites as well as the study delivery team) so that the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

Amendments to the original and approved study protocol and related documents will be notified to the Sponsor, HRA and University Medical School REC. Amendments will be notified to the lead NHS R&D office and communicated to the participating organisations (R&D office and local research team)

departments of participating sites, to assess whether the amendment affects the NHS permission for that site. When necessary, approval for the changes will be sought. The Chief Investigator will be responsible for all amendment decisions.

8.3 Peer review

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. This qualitative research protocol has additionally been reviewed by two experienced senior qualitative researchers based at the University of Exeter.

8.4 Patient & Public Involvement

A patient and healthcare professional partnership approach underpins the wider SAMueL-2 project in which these qualitative research studies are nested. Mr Leon Farmer is a PCI co-applicant on the programme grant research team and was invited to contribute to reviewing this Protocol and supporting study documents, alongside the rest of the members of the PCI group. The insights generated from the qualitative work will also be shared with patient and public representatives for their comment to develop interpretations and inform the wider dissemination of the qualitative findings.

This study is supported by the PenARC involvement team at the University of Exeter Medical School. The team has a track record of supporting people with complex needs to be research advisors. The PenARC PCI strategy and INVOLVE guidance is being followed (NIHR 2019; 2021).

. The PCI members are specifically involved in: approving the qualitative work design, reviewing key protocol documents, and discussing the research findings from the perspective of patients. A separate meeting with this group will discuss dissemination of the research findings. All involved patients and carers will have their travel fully reimbursed and their time recognised with a thank-you payment. PCI assistant Lauren Asare will provide tailored support in advance of, during and after meetings.

.

. Governance: One PCI person (who does not wish to be named) who cares for her husband with several health problems after a stroke is involved. Her husband has decided that she will contribute knowledge when he feels it is appropriate. As a carer representative, she also cared for her father after he had a stroke. One member of the PCI representation is a stroke survivor who will have a role similar to the carer representative.

8.5 Protocol compliance

Compliance will be monitored by the Chief Investigator (MA) who will review the progress of the qualitative research component against the protocol.

8.6 Data protection and patient confidentiality

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/).

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. 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. 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.

Data will be maintained in a secure and password protected encrypted computer folder on the University server. The linking code will be kept in a different folder on a different, encrypted computer and filed in a password protected folder, only identifiable to the named qualitative researcher KPB. KPB, IL and JF will be responsible for quality control, audit and analysis of data, reporting any problems to chief investigator MA and the Sponsor.

Personal contact details of participants will not be shared with anyone outside of the KPB and the CRN representative.

8.7 Indemnity

University of Exeter Indemnity Scheme will meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of this research. No arrangements for payment of compensation have been made in the event of harm to the research participants where no legal liability arises.

8.8 Access to the final study dataset

On completion of the study, the University of Exeter's institutional repository, SharePoint will store the final anonymised dataset, of which only the qualitative team (KPB, JF, IL & CP) will have access to. Data will be archived in the Secure Data Research Hub until all relevant research papers are published, then destroyed. Deanonymized data will be destroyed.

9 DISSEMINATION POLICY

9.1 Dissemination policy

Dissemination will be essential to the ML output and to NHS Trusts. We plan to submit papers generated from this work to peer-reviewed academic journals and to share the results at conferences for relevant academic and healthcare professional audiences. We will produce dissemination materials (reports and visual summaries) to share the findings with the participants in the study and the SAMueL-2 team. The dissemination of outputs will involve monthly consultations with the programme's PCI group who will input into and advise on materials for dissemination. NHS and PenARC will be acknowledged in any publications.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The final qualitative report, which will be a component of the full project report for NIHR (published in NIHR Journals) will be the primary responsibility of KPB, IL, JF and CP. All of the SAMueL-2 team will have an opportunity to review and input into the final qualitative report, and MA and MJ will give final sign-off. We adhere to The International Committee of Medical Journal Editors authorship criteria (ICMJE 2023)

10 REFERENCES

Aarons, C. Glisson, P. D. Green, K. Hoagwood, K. J. Kelleher, and J. A. Landsverk, "The organizational social context of mental health services and clinician attitudes toward evidence-based practice: a United States national study," Implement. Sci., vol. 7, no. 1, pp. 1–15, Jun. 2012, doi: 10.1186/1748-5908-7-56.

Bernard, H. R. (2018) *Research Methods in Anthropology: Qualitative and Quantitative Approaches*. 6th edn. London: Rowman & Littlefield.

The British Psychological Society, 2021. The British Psychological Society Code of Ethics. Available at: https://www.bps.org.uk/guidelines-and-policies. Accessed on 01.09.2022.

Broom, J. Adams, and P. Tovey, "Evidence-based healthcare in practice: A study of clinician resistance, professional de-skilling, and inter-specialty differentiation in oncology," Soc. Sci. Med., vol. 68, no. 1, pp. 192–200, Jan. 2009, doi: 10.1016/j.socscimed.2008.10.022.Allen, M., Pearn, K., Monks, T., et al. (2019) Can clinical audits be enhanced by pathway simulation and machine learning? An example from the acute stroke pathway. BMJ Open 2019;9:e028296. doi:10.1136/bmjopen-2018-028296.

Chaisinanunkul, N., Adeoye, O., Lewis, R.J. et al. (2015)., Adopting a Patient-Centered Approach to Primary Outcome Analysis of Acute Stroke Trials Using a Utility-Weighted Modified Rankin Scale. Stroke. 46: 2238-43.

Craig, J., Shore, J., Russell, J., & Jenks, M. (2019) National Institute for Health and Care Excellence Evidence Standards Framework for Digital Health Technologies Cost Consequences andBudget Impact Analyses and Data Sources. budget-impact-guide.pdf (nice.org.uk)

Cubellis L, Schmid C, von Peter S. Ethnography in Health Services Research: Oscillation Between Theory and Practice. *Qualitative Health Research*. 2021;31(11):2029-2040

De Brun A, Flynn D, Ternent L, et al. Factors that influence clinicians' decisions to offer intravenous alteplase in acute ischemic stroke patients with uncertain treatment indication: results of a discrete choice experiment. *International Journal of Stroke* 2018;13(1):74-82.

Dreyfus S, Dreyfus H. A five stage model of the mental activities involved in directed skill acquisition. California University Berkeley Operations Research Center [monograph on the Internet]; 1980. Available from: http://www.dtic.mil/dtic/index.html [downloaded 12 01 2023]

Dreyfus H, Dreyfus S. *Mind over machine: the power of human intuitive expertise in the era of the computer.* New York: Free Press; 1986.

Egan, T., & Jaye, C. (2009). Communities of clinical practice: the social organization of clinical learning. *Health*, *13*(1), 107–125.

Feigin VL, et al. Global and regional burden of stroke during 1990-2010: findings from the Global Burden of Disease Study 2010. Lancet. 2014;383(9913):245-54.

Gabbay J, le May A. Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care. BMJ. 2004 Oct 30;329(7473):1013.

Gladwin, C. 1980, “A Theory of Real-Life Choice: Applications to Agricultural Decisions.” In*Agricultural Decision Making: Anthropological Contributions to Rural Development*, P. Bartlett, ed. New York: Academic Press, pp. 45–85.

Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, Hinder S, Fahy N, Procter R, Shaw S. Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies J Med Internet Res 2017;19(11):e367

Greenhalgh, T. “What Is This Knowledge That We Seek to ‘Exchange’?,” Milbank Q., 88, [4] 492, Dec. 2010.

Goyal M, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. Lancet. 2016;387:1723-31.

Halford, S. 2021. *Doing the Future Differently: AI and the Promise of a New ‘Response-ability’*. [Podcast]. 2021. Available at: https://uk-podcasts.co.uk/podcast/anthropology-technology-conference/creating-emergent-socio-digital-futures-with-susan. (Accessed: 08.09.2022).

Health Research Authority. 2020. Research in Emergency Settings. [Online]. Available at: Research in emergency settings - Health Research Authority (hra.nhs.uk) Accessed 06.12.2022.

Hunink., M. Decision Making in Health and Medicine. Cambridge University Press, 2014.

International Committee of Medical Journal Editors. 2023. Defining the Roles of Authors and Contributors. Available at: ICMJE | Recommendations | Defining the Role of Authors and Contributors. Accessed 03.01.2023.

Johnson-Hanks, J. 2002. 'On the Limits of life Stages in Ethnography: Toward a Theory of Vital Conjunctures.' American Anthropologist 104 (3): 865–880.

Johnson-hanks, J. When the future decides: uncertainty and intentional action in contemporary Cameroon. Current Anthropology Volume 46, Number 3, June 2005

Krzyworzeka, A. 2013. 'Decision-making in Farming Households in Eastern Poland.' Focaal, Journal of Global and Historical Anthropology 65: 129–144.

Lyon, D., Tunåker, C., Pratt-Boyden, K. *Forthcoming*, Decision-Making among Local Neighbourhood Groups; The Case of 'Invisible Whispering'. *Social Anthropology.*

Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. Qualitative Health Research. 2016;26(13):1753-1760. doi:10.1177/1049732315617444

Ministry of Housing, Communities & Local Government. 2019. The English Indices of Deprivation 2019. Available at The English Indices of Deprivation 2019 (publishing.service.gov.uk) (Accessed: 08.08.2022).

National Health Service England. NHS England's Work on Stroke. 2021. [website]. Available at NHS England » NHS England's work on stroke. (Accessed: 10.09.2022).

---- "The NHS Long Term Plan," 2019. [Online]. Available: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf.[12]

NHS England and NHS Improvement, "National Stroke Service Model: Integrated Stroke Delivery Networks," 2021. Accessed: Jun. 14, 2021. [Online]. Available: https://www.england.nhs.uk/wp-content/uploads/2021/05/national-stroke-service-model-integrated-stroke-delivery-networks-may-2021.pdf.

National Institute for Clinical Excellence. Stroke and transient ischaemic attack in over 16s: diagnosis and initial management.; 2019.

National Institute for Health and Care Research. 2022. Equality, Diversity and Inclusion Strategy 2022-2027. Available at Equality, Diversity and Inclusion Strategy 2022-2027 | NIHR. (Accessed: 30.07.2022).

National Institute for Health and Care Research. 2019. PPI (Patient and Public Involvement) Resources for Applicants to NIHR Research Programmes. Available at PPI (Patient and Public Involvement) resources for applicants to NIHR research programmes | NIHR. (Accessed: 30.09.2022).

National Institute for Health and Care Research. 2019 PenARC Public Engagement Strategy 2019-24. Visions, Principles and Priorities for Researchers and Public Collaborators Working Together.

Available at https://arc-swp.nihr.ac.uk/wp/wp-content/uploads/2021/08/PenARC-Public-Engagement-Strategy-2019-24-v.2.1.pdf. (Accessed: 30.09.2022).

Ortiz, S. 1967. 'The Structure of Decision-Making Among Indians of Colombia.' In Themes in Economic Anthropology, edited by R. Firth, 191–227.

Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. Adm Policy Ment Health. 2015 Sep;42(5):533-44. doi: 10.1007/s10488-013-0528-y. PMID: 24193818; PMCID: PMC4012002.

Pope C, Mays N. Qualitative research in health care. Oxford: Blackwell 2006.

Royal College of Physicians. Clinical Effectiveness and Evaluation Unit on behalf of the Intercollegiate Stroke Working Party. Clinical audit second pilot public report: National results based on stroke patients admitted to and/or discharged from hospital between April–June 2013. http://www.rcplondon.ac.uk/sites/default/files/ssnap_public_report_2_-_national_level_results_april_-_june_2013_with_appendices.pdf

Royal Cornwall Hospitals NHS Trust. 2022. Risk Assessment and Management Strategy and Policy V9.2 November 2022. [Online] Available at: Risk Assessment and Management Strategy and Policy v9.2 (cornwall.nhs.uk). Accessed on: 11.11.2022.

Saver JL, et al. Time to Treatment With Endovascular Thrombectomy and Outcomes From Ischemic Stroke: A Meta-analysis. JAMA. 2016;316(12):1279-88.

Sentinel Stroke National Audit Programme. Annual Results Portfolio April 2015 March 2016. SSNAP, 2016.

SSNAP (2020) 'Sentinel Stroke National Audit Programme - Annual Results Portfolio'. Available at:https://www.strokeaudit.org/Documents/National/Clinical/Apr2019Mar2020/Apr2019Mar2020-AnnualResultsPortfolio.aspx

Stroke Unit Trialists Collaboration. Organised inpatient (stroke unit) care for stroke. Cochrane Database Syst Rev. 2013:CD000197.

Sjölander-Lindqvist, A., and S. Cinque. 2013. 'When Wolves Harm Private Property – Decision Making on State Compensation.' Focaal – Journal of Global and Historical Anthropology 65: 114–28.

Tai, J., Fischer, J. and Noble, C. 2021. Observational studies in health professional education research. *Focus on Health Professional Education: A Multi-Professional Journal*. 22, 1 (Mar. 2021), 94–111.

Tsoukas, H. and E. Vladimirou, "What is organizational knowledge?," J. Manag. Stud., vol. 38, no. 7, pp. 972–993, Nov. 2001, doi: 10.1111/1467-6486.00268.

University of Exeter. 2022. Temporary Policies due to Coronavirus. Available at : https://www.exeter.ac.uk/research/doctoralcollege/support/coronavirus/temporarypolicies/. Accessed: 07.10.2022.

Weston, L. E., Krein, S. and Harrod, M. (2022) “Using observation to better understand the healthcare context”, *Qualitative Research in Medicine and Healthcare*, 5(3)

Wardlaw JM, et al. Thrombolysis for acute ischaemic stroke. Cochrane Database Syst Rev. 2014;CD000213.

Xu XM, et al. The economic burden of stroke care in England, Wales and Northern Ireland: Using a national stroke register to estimate and report patient-level health economic outcomes in stroke. Eur Stroke J. 2018;3(1):82-91.

11. APPENDICES

11.1 Appendix 1- Required documentation

List here all the local documentation you require prior to initiating a participating site (e.g. CVs of the research team, Patient Information Sheet (PIS) on headed paper etc.).

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.

Participant Information Sheet
Observations

NHS physicians, commissioners, planners and other stroke care staff involved in thrombolysis

IRAS ID: 322303 Study Number Centre Number

Title of Project: Stroke Audit Machine Learning (SAMueL-2)

Name of Researcher: Dr Keira Pratt-Boyden

Invitation and brief summary:
We (The SAMueL-2 project team, at The University of Exeter) would like to invite you to take part in a period of focussed observation, as part of a study of using audit data and machine learning (ML) to help physicians make decisions around thrombolysis. This sheet will give you more information about the study, including what you would be asked to do if you decide to take part. You are welcome to ask any further questions about the study.

Our aim in SAMueL-2 is to improve the ways that information from the national stroke audit (Sentinel Stroke National Audit Programme, SSNAP) is used by physicians to inform the care they provide, with a focus on the use of intravenous thrombolysis in acute stroke pathways. We will work with physicians and other stroke care staff 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 staff's 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. ML is a type of artificial intelligence (AI) that learns patterns from historical data to predict new outcomes.

The three specific objectives being addressed by the qualitative aspect of this study are:

1) To understand 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 SSNAP and about the use of ML in improving clinical practice
3) To combine what we learn, and use this knowledge, alongside contributions from other stakeholders, to develop and refine the application of ML to national audit data

Please take time to consider this information carefully and if you wish, to ask the researcher questions.

Purpose of the research:
Stroke is the most common cause of severe adult disability, and outcomes can be significantly improved for selected patients though the use of time-critical treatments such as thrombolysis, which accelerates the breakdown of blood clots. For thrombolysis to be of benefit, it needs to be given as soon after the stroke as possible, but it is not appropriate for all patients and carries a small risk of intracranial haemorrhage.

SSNAP collects data on the processes and outcomes of stroke care for stroke admissions in England, Wales and Northern Ireland. SSNAP shows that the use of thrombolysis varies significantly, 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. The speed of thrombolysis delivery, from patient arrival, also varies widely, with some hospitals taking an average of 90 minutes and others taking less than 40 minutes to administer the drug.

SAMueL-2 will investigate how a ML-based approach to changing clinical practice can be designed and adapted to suit the needs of physicians with the aim of supporting the optimal implementation of thrombolysis. For example, our analysis helps to reveal differences between hospitals in treating different patient groups, such as those with mild stroke, those with pre-existing disability, and those with an imprecise stroke onset time. The qualitative component of SAMueL-2 will explore *how* physicians at a particular hospital use thrombolysis, in order to identify what will be of greatest value in reducing variation in its use. We will also 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 social and institutional contexts and conditions that influence this.

Why have I been approached?

We are approaching a number of clinical staff (including healthcare professionals and commissioners) who work with patients who have had a stoke to learn more about the processes and experiences of using audit data to optimise thrombolysis use. We want to observe how thrombolysis treatment works in hospitals- including how decisions to thrombolyse (or not) are made.

You have been given this information sheet because we are inviting you to be part of our observational study. We are hoping to recruit as many physicians and staff involved in stroke as possible in your Trust. All participants will be physicians and other stroke care health professionals, stakeholders or commissioners working across NHS Trusts who are involved in thrombolysis.

What would taking part involve?

A period of focussed observation will take place at your place of work and online for a maximum period of 2 weeks. You will not be asked to do anything different other than your regular duties. The researcher will be observing the stroke pathways, and how staff interact before, during and after a suspected stroke. She will also be present in other areas of the hospital, looking at stroke protocol and attending stroke review meetings. The observation will be conducted by a researcher from the University of Exeter Medical School: Keira Pratt-Boyden. Keira will not collect any personal identifying information about your patients.

What are the possible benefits of taking part?

Whilst there are no direct benefits of taking part in this study, being involved in this study will give you the opportunity to inform understandings of thrombolysis and ML use in stroke care.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages of taking part in this study.

How will we work safely to reduce the risk of COVID (SARS-CoV-2)?

While UK government restrictions have been removed for most day-to-day activities, the researcher will:

- Wear a suitable face covering
- Use hand sanitiser (some will be provided)
- Continue to review risk assessments against the current government guidelines
- Have completed an NHS research passport (Requiring a health check)
- Comply with any local arrangements which may be implemented at the time

For general guidance on living with COVID, please see the government page at: general guidance on living safely with respiratory infections including covid-19.
And for Exeter University guidance, please see; https://www.exeter.ac.uk/coronavirus/

What will happen if I don't want to carry on with the study?
You can stop taking part in the observation at any time and we will not require any reasons for stopping. You can ask the researcher to leave the room you are in, or if you prefer, you can email her at k.z.pratt-boyden@exeter.ac.uk or the PI at m.allen@exeter.ac.uk to opt out of the study. If you withdraw from the study, she may still be present in the hospital observing others, but will not observe any activities you undertake or collect or store information about you.

We will further anonymise data after it has been collected, which means that we will take 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. 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.

Withdrawing consent will not have any effect on you or your professional activities.

How will my information be kept confidential?
In 2018 regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a 'UK-only' version) and the DPA 2018 still applies.

The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the 'public interest'. The University continues to be transparent about its processing of your personal data and the participant information sheet should provide a clear explanation of how your data will be collected, processed, stored and destroyed. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information can be obtained from the University of Exeter's Data Protection Officer via the web-link:
https://www.exeter.ac.uk/aboutoursite/dataprotection/dpo/
If you have any concerns about how your data is controlled and managed for this study, then please contact the Sponsor Representative: Pam Baxter, Research Governance Manager (Contact details at the end of the information sheet).

With your consent, anonymised observational notes will be recorded by the researcher. Any reference to you will be by means of an anonymous study ID (number/letter) or pseudonym. These will be downloaded to a password protected and encrypted computer server. The data will be kept for until outputs are published and then destroyed.

The only people who will see the full and anonymised dataset for the workshops are Dr Michael Allen who is the principal investigator of this study, and researcher Keira Pratt-Boyden. Only the researcher will know who said what. Some anonymised quotes from the observational period may be used in dissemination (in presentations and reports) to illustrate the findings from the research.

Confidentiality may only be broken if the participant discloses a risk to themselves or others. In that case, researchers are obliged to share the information you provided with relevant services or authorities.

Your rights to access, to change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the anonymised information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible

How have patients, carers and/or the public been involved in this study?
Our PCI (Patient and carers involvement) group have been consulted at all stages of the study. They have reviewed this information sheet.

What will happen to the results of this study?
Results (including anonymised data) will be disseminated via academic publications, conferences, meetings with stakeholders (I.e. stroke physicians and NHS management professionals)

News, outcomes, information on the study and study progress is available throughout the period of study and afterward via https://samuel-book.github.io/samuel-1.

Who is organising and funding this study?
The sponsor for this study is the University of Exeter. This research is funded by the National Institute for Health Research grant number NIHR134326. The research team is based at The University of Exeter. The principal investigator is Dr Michael Allen: m.allen@exeter.ac.uk.

Who has reviewed this study?
This project has been reviewed by the Medical School Research Ethics Committee at the University of Exeter (Reference Number….) and assessed for compliance in the NHS by the Health Research Authority.

Further information and contact details
In the event of queries or requests you may contact me, the researcher, using the following contact information:
email Dr Keira Pratt-Boyden, University of Exeter, K.Z.Pratt-Boyden@exeter.ac.uk or by phone: (01392) 724086

To contact the Medical School Research Ethics Committee
please email C.Barkle@exeter.ac.uk

The sponsor for this study is the University of Exeter, and the contact name there is: Ms Pam Baxter p.r.baxter2@exeter.ac.uk.

Thank you for your interest in this project and for taking the time to read this information sheet.

Participant Information Sheet
Semi-Structured Interviews

NHS physicians, commissioners, planners and other stroke care staff involved in thrombolysis

IRAS ID: 322303 Study Number Centre Number

Title of Project: Stroke Audit Machine Learning (SAMueL-2)

Name of Researcher: Dr Keira Pratt-Boyden

Invitation and brief summary:
We (The University of Exeter) would like to invite you to take part in an interview, as part of a study of using audit data and machine learning (ML) to help physicians make decisions around thrombolysis. This sheet will give you more information about the study, including what you would be asked to do if you decide to take part. You are welcome to ask any further questions about the study.

Our aim in SAMueL-2 is to improve the ways that information from the national stroke audit (Sentinel Stroke National Audit Programme, SSNAP) is used by physicians to inform the care they provide, with a focus on the use of intravenous thrombolysis in acute stroke pathways. We will work with physicians and other stroke care staff 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 staff's views, experiences, and current practices concerning thrombolysis, machine learning (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. ML is a type of artificial intelligence (AI) that learns patterns from historical data to predict new outcomes.

The three specific objectives being addressed by the qualitative aspect of this study are:

4) To understand how thrombolysis is currently delivered, centered on physicians' views, understandings, and practices
5) To learn more about how stroke physicians and staff think and feel about SSNAP and about the use of ML in improving clinical practice
6) To combine what we learn, and use this knowledge, alongside contributions from other stakeholders, to develop and refine the application of ML to national audit data

Please take time to consider this information carefully and if you wish, to ask the researcher questions.

Purpose of the research:
Stroke is the most common cause of severe adult disability, and outcomes can be significantly improved for selected patients though the use of time-critical treatments such as thrombolysis, which accelerates the breakdown of blood clots. For thrombolysis to be of benefit, it needs to be given as soon after the stroke as possible, but it is not appropriate for all patients and carries a small risk of intracranial haemorrhage. SSNAP collects data on the processes and outcomes of stroke care (up to 6 months post-stroke) for stroke admissions in England, Wales and Northern Ireland. SSNAP shows that the use of thrombolysis varies significantly, 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. The speed of thrombolysis delivery, from patient arrival, also varies widely, with some hospitals taking an average of 90 minutes and others taking less than 40 minutes to administer the drug.

SAMueL-2 will investigate how a ML-based approach to changing clinical practice can be designed and adapted to suit the needs of physicians with the aim of supporting the optimal implementation of thrombolysis. For example, the analysis helps to reveal differences between hospitals in treating different patient groups, such as those with mild stroke, those with pre-existing disability, and those with an imprecise stroke onset time. The qualitative component of SAMueL-2 will explore *how* physicians at a particular hospital use thrombolysis, in order to identify what will be of greatest value in reducing variation in its 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 social and institutional contexts and conditions that influence this.

Why have I been approached?
We are approaching a number of clinical staff (including healthcare professionals or commissioners) who work with patients who have had a stoke, across several different hospitals nationally to learn more about the processes and experiences of using audit data to optimise thrombolysis use. A researcher will interview physicians about thrombolysis use, machine learning, and how the results from the modelling work can best be presented in a way that is useful to them. We have used SSNAP to identify where thrombolysis is frequently used, and where it is rarely used. This is so that we can compare reasons for why thrombolysis use vary. We also want to interview a variety of stroke grades and specialisms.

You have been given this information sheet because we are inviting you to take part in an interview. We are hoping to recruit up to 20 people in total.

What would taking part involve?
Interviews will be approximately one hour long. You will be interviewed by a Researcher from the University of Exeter College of Medicine; Dr Keira Pratt-Boyden. She will come to your place of work, unless you prefer to be interviewed on the phone/online. In the interview she will ask you how you deliver stroke care and how you make decisions regarding thrombolysis. You will also be asked for your thoughts and experiences of machine learning in strokecare. The interview will be recorded using a GDPR compliant, encrypted recording device.

Time, place and date of the interview will be agreed between you and the researcher, at your convenience (I.e., in or out outside of your working hours). We need to complete all interviews by December 2023.

What are the possible benefits of taking part?
Whilst there are no direct benefits of taking part in this study, being involved in this study will give you the opportunity to inform understandings of thrombolysis and ML use in stroke care.

What are the possible disadvantages and risks of taking part?
We do not foresee any disadvantages of taking part in this study. If you were to find anything discussed during the interview distressing, we would advise you to contact your employer and relevant wellbeing organisation.

How will we work safely to reduce the risk of COVID (SARS-CoV-2)?
While UK government restrictions have been removed for most day-to-day activities, as researchers, we will:

- Wear a suitable face covering
- Use hand sanitiser (some will be provided)
- Continue to review risk assessments against the current government guidelines

- Have completed an NHS research passport (Requiring a health check)
- Comply with any local arrangements which may be implemented at the time

For guidance the following UK government page has general guidance on living safely with respiratory infections including covid-19. And for Exeter University guidance, please see; https://www.exeter.ac.uk/coronavirus/

What will happen if I don't want to carry on with the study?
You can stop taking part in the interview at any time and we will not require any reasons for stopping.

We will anonymise data after it has been collected, which means that we will take out any personal identifying information. There will be a week or two between us collecting the data and us anonymising it, when people can withdraw their consent for us to use the data. 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.

Withdrawing consent will not have any effect on you or your professional activities.

How will my information be kept confidential?
In 2018 regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a 'UK-only' version) and the DPA 2018 still applies.

The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the 'public interest'. The University continues to be transparent about its processing of your personal data and the participant information sheet should provide a clear explanation of how your data will be collected, processed, stored and destroyed. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information can be obtained from the University of Exeter's Data Protection Officer via the web-link: https://www.exeter.ac.uk/aboutoursite/dataprotection/dpo/
If you have any concerns about how your data is controlled and managed for this study, then please contact the Sponsor Representative: Pam Baxter, Research Governance Manager (Contact details at the end of the information sheet).

With your consent, the interview will be audio recorded by the researcher. The audio will be then downloaded to a password protected and encrypted computer server. And forwarded to a typist who has signed a confidentiality agreement. The audio recording will be transcribed (typed) and anonymised. The data will be kept until results have been published and then destroyed. Any reference to you will be by means of an anonymous study ID (number/letter) or pseudonym.

The only people who will see the full and anonymised dataset for the workshops are Dr Michael Allen who is the principal investigator of this study, and researcher Keira Pratt-Boyden. Some anonymised quotes from the observational period may be used in dissemination (in presentations and reports) to illustrate the findings from the research.

Your rights to access, to change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the anonymised information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible

Confidentiality may only be broken if the participant discloses a risk to themselves or others. In that case, researchers are obliged to share the information you provided with relevant services or authorities.

News/outcomes of the study and study progress is available via https://samuel-book.github.io/samuel-1.

How have patients, carers and/or the public been involved in this study?
Our PCI (Patient and carers involvement) group have been consulted at all stages of the study. They have reviewed this information sheet.

What will happen to the results of this study?
Results (including anonymised data) will be disseminated via academic publications, conferences, meetings with stakeholders (I.e. stroke physicians and NHS management professionals)

Information on the outcomes of the project are readily available to participants via https://samuel-book.github.io/samuel-1.

Who is organising and funding this study?
The sponsor for this study is the University of Exeter. This research is funded by the National Institute for Health Research grant number NIHR134326. The research team is based at The University of Exeter. The principle investigator is Dr Michael Allen: m.allen@exeter.ac.uk.

Who has reviewed this study?
This project has been reviewed by the Medical School Research Ethics Committee at the University of Exeter (Reference Number….) and assessed for compliance in the NHS by the Health Research Authority.

Further information and contact details
In the event of queries or requests you may contact me using the following contact information.
Please email Dr Keira Pratt-Boyden, University of Exeter, K.Z.Pratt-Boyden@exeter.ac.uk or by phone: (01392) 724086

To contact the Medical School Research Ethics Committee
please email C.Barkle@exeter.ac.uk

The sponsor for this study is the University of Exeter, and the contact name there is: Ms Pam Baxter p.r.baxter2@exeter.ac.uk.

Thank you for your interest in this project and for taking the time to read this information sheet.

Participant Information Sheet
Co-production Workshops

NHS physicians and other stroke care staff involved in thrombolysis

IRAS ID: 322303 Study Number Centre Number

Title of Project: Stroke Audit Machine Learning (SAMueL-2)

Name of Researcher: Dr Keira Pratt-Boyden

Invitation and brief summary:
We (The SAMueL-2 team at The University of Exeter) would like to invite you to take part in a co-production workshop with other staff involved in thrombolytic decision making and practice, as part of a study of using audit data and machine learning (ML) to help physicians make decisions around thrombolysis. This sheet will give you more information about the study, including what you would be asked to do if you decide to take part. You are welcome to ask any further questions about the study.

Our aim in SAMueL-2 is to improve the ways that information from the national stroke audit (Sentinel Stroke National Audit Programme, SSNAP) is used by physicians to inform the care they provide, with a focus on the use of intravenous thrombolysis in acute stroke pathways. We will work with physicians and other stroke care staff 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 staff's views, experiences, and current practices concerning thrombolysis, machine learning (ML), and SSNAP. The things we learn from staff involved in thrombolysis will shape the design, contents, and implementation of our ML work. ML is a type of artificial intelligence (AI) that learns patterns from historical data to predict new outcomes.

The three specific objectives being addressed by the qualitative aspect of this study are:

7) To understand how thrombolysis is currently delivered, centered on physicians' views, understandings, and practices
8) To learn more about how stroke physicians and staff think and feel about SSNAP and about the use of ML in improving clinical practice
9) To combine what we learn, and use this knowledge, alongside contributions from other stakeholders, to develop and refine the application of ML to national audit data

Please take time to consider this information carefully and to discuss it with family or friends if you wish, or to ask the researcher questions.

Purpose of the research:
Stroke is the most common cause of severe adult disability, and outcomes can be significantly improved for selected patients though the use of time-critical treatments such as thrombolysis, which accelerates the

breakdown of blood clots. For thrombolysis to be of benefit, it needs to be given as soon after the stroke as possible, but it is not appropriate for all patients and carries a small risk of intracranial haemorrhage. SSNAP collects data on the processes and outcomes of stroke care (up to 6 months post-stroke) for stroke admissions in England, Wales and Northern Ireland. SSNAP shows that the use of thrombolysis varies significantly, 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. The speed of thrombolysis delivery, from patient arrival, also varies widely, with some hospitals taking an average of 90 minutes and others taking less than 40 minutes to administer the drug.

SAMueL-2 will investigate how a ML-based approach to changing clinical practice can be designed and adapted to suit the needs of physicians with the aim of supporting the optimal implementation of thrombolysis. For example, the analysis helps to reveal differences between hospitals in treating different patient groups, such as those with mild stroke, those with pre-existing disability, and those with an imprecise stroke onset time. The qualitative component of SAMueL-2 will explore *how* physicians at a particular hospital use thrombolysis, in order to identify what will be of greatest value in reducing variation in its 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 social and institutional contexts and conditions that influence this.

Why have I been approached?

We are approaching a number of clinical staff (including healthcare professionals or commissioners) who work with patients who have had a stoke to learn more about the processes and experiences of using audit data to optimise thrombolysis use.

You have been given this information sheet because we are inviting you to a co-production workshop using machine learning (ML) findings from the SSNAP data to explore decision-making around thrombolysis. We are hoping to recruit up to 5 participants to be involved in this workshop to feedback our findings so far and to discuss the research and its implications. All participants will be physicians and other stroke care health professionals, stakeholders or commissioners working across NHS Trusts who are involved in thrombolysis.

What would taking part involve?

Co-production workshops will be approximately one hour long and will take place at your place of work or online, at a time agreed by the participant group (in or out of working hours). Alongside up to 5 other NHS stroke care physicians, professionals or stroke commissioners, you will be asked to discuss findings from ML analysis of patient data in SSNAP. The workshop will be led by a researcher from the University of Exeter College of Medicine: Keira Pratt-Boyden. An administrator may be present to support Keira. Data from the workshop will be audio recorded on an encrypted password protected audio device and stored on a secure system.

The group will be obeying the Chatham House Rule, which is that participants agree not to share information about other individual participants beyond the co-production workshop. Further, participants are asked not to use identifying information when discussing patient cases.

What are the possible benefits of taking part?

Whilst there are no direct benefits of taking part in this study, being involved in this study will give you the opportunity to inform understandings of thrombolysis and ML use in stroke care.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages of taking part in this study, but it does require your time for the workshop: approximately one hour. If you were to find any of the discussion in the workshop distressing, we would advise you to contact your employer and relevant wellbeing organisation.

How will we work safely to reduce the risk of COVID (SARS-CoV-2)?

While UK government restrictions have been removed for most day-to-day activities, for our co-production workshop, we recommend that all participants:

- Wear a suitable face covering
- Use hand sanitiser (some will be provided)

As researchers, we will:

- Continue to review risk assessments against the current government guidelines
- Wear a suitable face covering
- Use hand sanitiser
- Have completed an NHS research passport (Requiring a health check)
- Comply with any local arrangements which may be implemented at the time

For guidance the following UK government page has general guidance on living safely with respiratory infections including covid-19. And for Exeter University guidance, please see;
https://www.exeter.ac.uk/coronavirus/

What will happen if I don't want to carry on with the study?
You can stop taking part in the workshop at any time and we will not require any reasons for stopping the workshop.

We will anonymise all data after it has been collected, which means that we will take out any personal identifying information. There will be a week or two between us collecting the data and us anonymising it, when people can withdraw their consent for us to use the data. 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.

Withdrawing consent will not have any effect on you or your professional activities.

How will my information be kept confidential?
In 2018 regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a 'UK-only' version) and the DPA 2018 still applies.

The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the 'public interest'. The University continues to be transparent about its processing of your personal data and the participant information sheet should provide a clear explanation of how your data will be collected, processed, stored and destroyed. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information can be obtained from the University of Exeter's Data Protection Officer via the web-link:
https://www.exeter.ac.uk/aboutoursite/dataprotection/dpo/
If you have any concerns about how your data is controlled and managed for this study, then please contact the Sponsor Representative: Pam Baxter, Research Governance Manager (Contact details at the end of the information sheet).

With your consent, the workshop will be audio recorded. The audio will be then downloaded to a password protected and encrypted computer server. And forwarded to a typist who has signed a confidentiality agreement. The audio recording will be transcribed (typed) and anonymised. The audio recording will then be destroyed. All other data will be kept until results have been published, then destroyed.

The researcher may also take notes, (using codes instead of your name) which she will destroy securely as soon as they have been uploaded to a password protected and encrypted computer server. She will do this 48 hours after the workshop has ended. Any reference to you will be by means of an anonymous study ID

(number/letter) or pseudonym, to ensure your information will be protected and cannot be identified outside of the research team.

Your rights to access, to change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the anonymised information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The only people who will see the full and anonymised dataset for the workshops are Dr Michael Allen who is the principal investigator of this study, and researcher Keira Pratt-Boyden. Some anonymised quotes from the workshops may be used in dissemination (in presentations and reports) to illustrate the findings from the research.

Confidentiality may only be broken if the participant discloses a risk to themselves or others. In that case, researchers are obliged to share the information you provided with relevant services or authorities.

News/outcomes of the study and study progress is available via https://samuel-book.github.io/samuel-1.

Will I receive any payment for taking part?
Each participating participant will be eligible for a £40 voucher in acknowledgement of your time contributed. The £40 can also be nominated by the participant to be donated as a charitable contribution to Medicins Sans Frontiers.

How have patients, carers and/or the public been involved in this study?
Our PCI (Patient and carers involvement) group have been consulted at all stages of the study. They have reviewed this information sheet.

What will happen to the results of this study?
Results (including anonymised data) will be disseminated via academic publications, conferences, meetings with stakeholders (I.e. stroke physicians and NHS management professionals)

Information on the outcomes of the project is readily available to participants via https://samuel-book.github.io/samuel-1.

Who is organising and funding this study?
The sponsor for this study is the University of Exeter. This research is funded by the National Institute for Health Research grant number NIHR134326. The research team is based at The University of Exeter. The principal investigator is Dr Michael Allen: m.allen@exeter.ac.uk.

Who has reviewed this study?
This project has been reviewed by the Medical School Research Ethics Committee at the University of Exeter (Reference Number….) and assessed for compliance in the NHS by the Health Research Authority.

Further information and contact details
In the event of queries or requests you may contact me using the following contact information.
Please email Dr Keira Pratt-Boyden, University of Exeter, K.Z.Pratt-Boyden@exeter.ac.uk or by phone: (01392) 724086

To contact the Medical School Research Ethics Committee
please email C.Barkle@exeter.ac.uk

The sponsor for this study is the University of Exeter, and the contact name there is: Ms Pam Baxter p.r.baxter2@exeter.ac.uk.

You can also contact the University Research Ethics and Governance Team

please email cgr-reg@exeter.ac.uk,

Thank you for your interest in this project and for taking the time to read this information sheet.

Script for Verbal Consent (Observation)

IRAS ID: 322303 Study Number Centre Number

Title of Project: **Stroke Audit Machine Learning (SAMueL-2)**

Name of Researcher: Dr Keira Pratt-Boyden

Introduction: Hello [again], my name is [Keira Pratt-Boyden]. I'm currently a researcher at the University of Exeter Medical School, working on a project entitled Stroke Audit Machine Learning.

- In this study, I want to investigate how physicians make decisions around thrombolysis. I also want to understand how we might use machine learning to help staff make decisions around thrombolysis. If you choose to be a part of this project, here is what will happen:
- I will observe you, and other stroke staff, as you move about your daily tasks, focussing in particular on the stroke pathways.
- With your permission, I would like to take observational notes [by hand/ on an encrypted tablet] and will store your data safely and confidentially on my University's secure system. I will destroy the research data after publication.
- The observation data will be anonymised. The anonymised data will form the basis of a research publication. It will not be easy to identify you in any publications or other research outputs.
- I would also like your permission to keep your contact details securely so that I can re-contact you if I need to clarify anything, or to potentially invite you to an interview.
- In order to reduce any potential risks related to Covid, I will wear a face covering, use hand sanitiser regularly and am fully vaccinated.
- You don't have to take part; you can ask me any questions you want before or throughout; you can choose to stop observation at any time or ask me to leave the room. Alternatively, you can email Mike Allen (the chief investigator) if you have any problems at m.allen@exeter.ac.uk. After the observation, you can withdraw your information/ data before it is fully anonymised.
- The project will be published in an academic journal(s) and website and presented at conferences and input into machine learning modelling.
- If you have any complaints or concerns please feel free to contact me. My phone number is (01392) 724086. You can also reach me at k.z.pratt-boyden@exeter.ac.uk.

- This research project has been reviewed and approved by The University of Exeter Medical School Research ethics committee. The ethics reference is [**Rxxx**]. If, after contacting me with any concern, you're still unhappy and wish to make a formal complaint, please contact the ethics committee. The sponsor representative's email address is p.r.baxter2@exeter.ac.uk.
- Do you have any questions?
- Do you give your permission for me to record observational data about you?
- [If applicable] Do you give permission for me to re-contact you to clarify information?
- Do you give me permission to quote you directly without identifying you?
- Are you happy to take part?

Ok, thanks, let's start.

CONSENT FORM Individual Interviews

Title of Project: **Stroke Audit Machine Learning (SAMueL-2)**

Name of Researcher: Dr Keira Pratt-Boyden

Study Number: IRAS ID: 322303 Centre Number: Participant Identification Number for this study:

Please initial box

1. I confirm that I have read the information sheet dated.....(version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐

3. I understand that relevant sections of data collected during the study, may be looked at by individuals from the University of Exeter, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data. ☐

4. I understand that taking part involves anonymised interview transcripts to be used for the purposes of the SAMueL-2 study and kept in an archive before outputs have been published. They will then be destroyed. ☐

5. I understand that anonymised data will be used in academic publications, in teaching and training materials, and in media reports. ☐

6. I understand that the information held and maintained by the researcher from the SAMueL-2 research team (The Department of Health and Community Sciences, University of Exeter Medical School), as well as representatives from the CRN (Clinical Research Network) may be kept securely and used to help contact me or provide information about the study. ☐

7. I agree to take part in the above study. ☐

Name of Participant **Date** **Signature**

Name of Person seeking consent **Date** **Signature**

CONSENT FORM Co-Production workshop

Title of Project: Stroke Audit Machine Learning (SAMueL-2)

Name of Researcher: Dr Keira Pratt-Boyden

Study Number: IRAS ID: 322303 Participant Identification Number for this study:

Please initial box

8. I confirm that I have read the information sheet dated..... (version....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

9. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐

10. I understand that relevant sections of data collected during the study, may be looked at by select individuals from the University of Exeter where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data. ☐

11. I will not share information about, or from, participants who attended the co-production workshop outside the workshop ☐

12. I understand that taking part involves the creation of anonymised workshop transcripts to be used for the purposes of the SAMueL-2 study and kept in a University archive before outputs have been published. They will then be destroyed. ☐

13. I understand that anonymised data will be used in academic publications, in training materials, and in media reports. ☐

14. I understand that the information held and maintained by the researcher from the SAMueL-2 research team (The Department of Health and Community Sciences, University of Exeter Medical School) as well as representatives from the CRN (Clinical Research Network) may be kept securely to help contact me or provide information about the study. ☐

15. I agree to take part in the above study. ☐

Name of Participant:	**Date**	**Signature**
Name of Person seeking consent:	**Date**	**Signature**

Stroke Audit Machine Learning (SAMueL-2)

Healthcare Professionals Topic Guide: Interviews

Introduction to project and consent

- Introduction: project, aims and expected outcomes, purpose of interview, and how long the interview should last.
- Inform participant they can ask for clarification on questions or choose not to answer.
- Verbally confirm ethical issues around confidentiality, anonymity and right to withdraw/end interview at any stage without reason.
- Receive written consent and ask permission to audio record interview.

Background and experience of thrombolysis

- Ask briefly about background: How long working in your current position? (education, employment, months/years of experience and fields of experience. Role in thrombolysis improvement/management or governance)
- Describe your personal experiences of thrombolysis improvement initiatives. What has helped? What has not worked so well?
- Identify non-clinical factors or resources when making decisions about whether to administer thrombolysis for acute stroke? What are most important in decision-making? (local/ national guidance, colleagues, centre culture, patient preference)
    - How do individuals think about and reflect on “Evidence”?
    - Confidence in local methods and protocols around decision making?
- Confidence in the evidence-base for decision making, including SSNAP. Sources of uncertainty/grey areas.

What are the human and technological processes by which we get AI adopted into a national audit?

- Check general understanding and perceptions of the use of AI: computer simulation, pathway modelling and machine learning.
- What data would SSNAP need to provide for them to be able to make better decisions about when to give/not give thrombolysis? If not SNAAP, what else? Why?
- What (might) needs to happen for new tech to be introduced in a particular hospital/setting?
- Is there anything else that they want to tell us about ML, SNAAP or evidence base for thrombolysis?

Stroke Audit Machine Learning (SAMueL-2)

Physician Topic Guide: Interviews

Introduction to project and consent

- Introduction: project, aims and outcomes, purpose of interview, and how long the interview should last.
- Inform participant they can ask for clarification on questions or choose not to answer.
- Verbally confirm ethical issues around confidentiality, anonymity and right to withdraw/end interview at any stage without reason.
- Receive written consent and ask permission to audio record interview.

Questions: Clinician background and experience of thrombolysis

- Ask briefly about background: How long working in your current position? (education, employment, months/years of experience and fields of experience, number of years treating acute stroke patients). How long offering thrombolysis, where based now?
- How often assess acute stroke patients for thrombolysis
- Describe the typical assessment and decision-making process for thrombolysis that occurs for these patients at this centre.
- Identify clinical and non-clinical factors or resources when making decisions about whether to administer thrombolysis for acute stroke? What are most important in decision-making? (local/ national guidance, colleagues, centre culture, patient preference)
    - 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?
- Confidence in local methods and protocols around decision making?
    - Who do physicians speak to when they are or have been uncertain what to do? This might be in response to new information (perhaps from guidelines, SNAAP, or research), in thinking about types of situation, or in reflecting on a situation in which they were unsure of how to proceed.
- Confidence in the evidence-base for decision making. Sources of uncertainty/grey areas

How modelling, machine learning and data might influence decision making: What are the human and technological processes by which we get AI adopted into a national audit?

- Check general understanding and perceptions of the use of AI: computer simulation, pathway modelling and machine learning.
- How aware of SNAAP and other stroke evidence bases? What do they think of the data? What data would SSNAP need to provide for them to be able to make better decisions about when to give/not give thrombolysis? If not SNAAP, what else? Why?

- 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 falling/ declining?)
- What are the barriers and facilitators to using these approaches (ML) in clinical practice?
- What (might) needs to happen for new tech to be introduced in a particular hospital/setting?
- Is there anything else that they want to tell us about ML, SNAAP or evidence base for thrombolysis?

The Stroke Audit Machine Learning (SAMueL-2) study

Physician Recruitment Script

Dear [Physician],

My name is [Name], and I am a [CRN stroke network nurse] in the Southwest Peninsula.

A research team from the University of Exeter Medical School are conducting a study about the use of simulation and machine learning with Sentinel Stroke National Audit Programme (SNAAP) data to help maximize the benefit of using intravenous thrombolysis in acute stroke – the project is called SAMueL-2 for short.

This research study is using machine learning technologies to provide feedback to stroke physicians on the use of thrombolysis. We are doing the project with SSNAP and a key objective is to explore the potential to include the innovations we're developing as part of the quarterly SSNAP returns to stroke teams. We are using qualitative research, which will be undertaken to explore the acceptability and potential influence of the approaches we're developing.

We are using machine learning to explore how different groups of physicians might approach thrombolysis in individual cases, and would like to explore the potential value in feeding back the results of this to stroke physicians to stimulate reflection on the approach to thrombolysis.

I am contacting you on behalf of Dr Mike Allen, Senior modeler and Chief Investigator for the SAMueL-2 study, and Prof Martin James, Stroke Physician in Exeter, to invite you to participate in the study. If you agree, you will be invited to an individual interview, depending on the phase of the study and also the level of interest in your team. A researcher, Dr Keira Pratt-Boyden will send you an information sheet, and if wish to participate, will arrange to come to your place of work and ask you about your views on thrombolysis use and/or whether modelling and feedback could help develop more consistent stroke care across the UK. This may involve the researcher showing you different visual representations of stroke data from our modelling research.

The individual interview will take no more than 60 minutes. Participation in this study is voluntary and you can leave the interview at any time if you change your mind. Your identity as a participant and your place of work will remain confidential during and after the study.

If you have questions or would like to participate, please contact me (Keira Pratt-Boyden), at The University of Exeter College of Medicine and Health, K.Z.Pratt-Boyden@exeter.ac.uk or phone: (01392) 724086

If you would like to participate, please complete the **consent to contacted form** and return it to Dr. Keira Pratt-Boyden, who is part of the research team at the University of Exeter, or us (the CRN) who will arrange for Keira to contact you directly to arrange an interview.

Thank you for your participation,

[Name] CRN Stroke Network [full contact information]

Consent to be contacted: Stroke staff

IRAS ID: 322303 Study Number Centre Number

Title of Project: **Stroke Audit Machine Learning (SAMueL-2)**

Name of Researcher: Dr Keira Pratt-Boyden

You have been given this form because, after receiving verbal and written information about the SAMueL-2 study, you have indicated willingness to be involved in a period of observation for the study.

By signing this form, you agree to be contacted by Dr Keira Pratt-Boyden, a qualitative researcher at the University of Exeter Medical School. She may contact you to clarify anything she observed, and can answer any further questions you may have.

Consent for your participation in observation will be taken on the day of the observation, before observation starts.

You can withdraw your consent to be contacted at any time, and at that point all of your contact details will be deleted from the study folders.

Your contact details will include: Your name, email address and/or phone number.

All personal data will be kept on a password-protected, encrypted university folder. We will not keep any paper copies containing personal data. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection

I hereby consent to be contacted by Dr Keira Pratt-Boyden:

Name:

Title and job role:

Address:

Email:

Phone number:

Secretary's name, email and phone number:

Name of Participant (PRINT) **Date** **Signature**

Please return signed form to Keira in person, or at k.z.pratt-boyden@exeter.ac.uk

Consent to be contacted: Stroke staff

IRAS ID: 322303 Study Number Centre Number

Title of Project: **Stroke Audit Machine Learning (SAMueL-2)**

Name of Researcher: Dr Keira Pratt-Boyden

You have been given this form because, after receiving verbal and written information about the SAMueL-2 study, you have indicated willingness to be interviewed for the study.

By signing this form, you agree to be contacted by Dr Keira Pratt-Boyden, a qualitative researcher at the University of Exeter Medical School. She will contact you with a view to scheduling an interview, and can answer any further questions you may have.

Consent for your participation in an interview will be taken on the day of the interview, before the interview starts.

You can withdraw your consent to be contacted at any time, and at that point all of your contact details will be deleted from the study folders.

Your contact details will include: Your name, email address and/or phone number.

All personal data will be kept on a password-protected, encrypted university folder. We will not keep any paper copies containing personal data. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection

I hereby consent to be contacted by Dr Keira Pratt-Boyden:

Name:

Title and job role:

Address:

Email:

Phone number:

Secretary's name, email and phone number:

Name of Participant (PRINT) **Date** **Signature**

Please return signed form to Keira in person, or at k.z.pratt-boyden@exeter.ac.uk

Consent to be contacted: Stroke staff

IRAS ID: 322303 Study Number Centre Number

Title of Project: **Stroke Audit Machine Learning (SAMueL-2)**

Name of Researcher: Dr Keira Pratt-Boyden

You have been given this form because, after receiving verbal and written information about the SAMueL-2 study, you have indicated willingness to be involved in a co-production workshop for the study.

By signing this form, you agree to be contacted by Dr Keira Pratt-Boyden, a qualitative researcher at the University of Exeter Medical School. She will contact you with a view to scheduling the workshop, and can answer any further questions you may have.

Consent for your participation in the workshop will be taken on the day of the workshop, before it starts.

You can withdraw your consent to be contacted at any time, and at that point all of your contact details will be deleted from the study folders.

Your contact details will include: Your name, email address and/or phone number.

All personal data will be kept on a password-protected, encrypted university folder. We will not keep any paper copies containing personal data. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection

I hereby consent to be contacted by Dr Keira Pratt-Boyden:

Name:
Title and job role:
Address:
Email:
Phone number:
Secretary's name, email and phone number:

Name of Participant (PRINT) **Date** **Signature**

Please return signed form to Keira in person, or at k.z.pratt-boyden@exeter.ac.uk

Consent to be contacted: Clinical stroke staff

IRAS ID: 322303 Study Number Centre Number

Title of Project: **Stroke Audit Machine Learning (SAMueL-2)**

Name of Researcher: Dr Keira Pratt-Boyden

You have been given this form because, after receiving verbal and written information about the SAMueL-2 study, you have indicated willingness to be involved in a period of observation for the study.

By signing this form, you agree to be contacted by Dr Keira Pratt-Boyden, a qualitative researcher at the University of Exeter Medical School. She may contact you to clarify anything she observed, and can answer any further questions you may have.

Consent for your participation in observation will be taken on the day of the observation, before observation starts.

You can withdraw your consent to be contacted at any time, and at that point all of your contact details will be deleted from the study folders.

Your contact details will include: Your name, email address and/or phone number.

All personal data will be kept on a password-protected, encrypted university folder. We will not keep any paper copies containing personal data. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection

I hereby consent to be contacted by Dr Keira Pratt-Boyden:

Name:

Title and job role:

Address:

Email:

Phone number:

Secretary's name, email and phone number:

Name of Participant (PRINT) **Date** **Signature**

Please return signed form to Keira in person, or at k.z.pratt-boyden@exeter.ac.uk

Consent to be contacted: Clinical stroke staff

IRAS ID: 322303 Study Number Centre Number

Title of Project: **Stroke Audit Machine Learning (SAMueL-2)**

Name of Researcher: Dr Keira Pratt-Boyden

You have been given this form because, after receiving verbal and written information about the SAMueL-2 study, you have indicated willingness to be interviewed for the study.

By signing this form, you agree to be contacted by Dr Keira Pratt-Boyden, a qualitative researcher at the University of Exeter Medical School. She will contact you with a view to scheduling an interview, and can answer any further questions you may have.

Consent for your participation in an interview will be taken on the day of the interview, before the interview starts.

You can withdraw your consent to be contacted at any time, and at that point all of your contact details will be deleted from the study folders.

Your contact details will include: Your name, email address and/or phone number.

All personal data will be kept on a password-protected, encrypted university folder. We will not keep any paper copies containing personal data. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection

I hereby consent to be contacted by Dr Keira Pratt-Boyden:

Name:

Title and job role:

Address:

Email:

Phone number:

Secretary's name, email and phone number:

Name of Participant (PRINT) **Date** **Signature**

Please return signed form to Keira in person, or at k.z.pratt-boyden@exeter.ac.uk

College of Medicine and Health Research Ethics Committee

Peer Review Form

Name of Reviewer:	Dr Conny Guell
Employing Organisation:	University of Exeter
Qualifications and area of expertise (needs to be an expert in the methods to be used or proposed topic for this project):	MA, MSc, MSc, PhD in Anthropology; Senior Lecturer, expert in qualitative research methods including ethnography / participant observation and experience in HRA ethics applications for qualitative research
Details of any potential conflict of interest:	none
Name of Researcher:	Keira Pratt-Boyden / Julia Frost
Project Title:	Stroke Audit Machine Learning SAMueL 2 Qualitative Study

What is your overall assessment of the quality of the study? Is there a clear research question/aim? Are the methods of data collection appropriate and adequately described? Are the methods of data analysis appropriate and adequately described?

Major points:

Overall, this is a very carefully thought through and detailed research protocol that takes into account potential sensitivities for and time constraints of health professional as study participants. The three work packages have been planned out in detail and potential ethical considerations well described throughout. All methods, including for data analysis are appropriate and have been adequately described.

Minor points:

What specific improvements would you like to see the applicant make in relation to the quality of the study?.

Major improvements:

I have no major improvements to recommend. A highly experienced team has developed the research protocol.

Minor improvements:

One query I have is how the researcher will be guided in observing decision making, particularly as the researcher does not seem to have a clinical background. Great to see the observational topic guide, which looks very comprehensive and goes some way to explaining what the researcher will pay attention to. A brief added explanation in the protocol how it will be used would be helpful.

What is your opinion of the originality, reliability and importance of the study?

This seems a study of high importance, developed by a highly experienced team and has been peer reviewed and received funding by the NIHR. I particularly commend the use of ethnographic / observational methods and thinking through practicalities in an acute clinical setting, including how to alert 'incidental participants' during observations through posters and the availability of PIS forms.

Lastly, are there any potential ethical issues/risks you would like to bring to the attention of the Committee?

Major issues/risks:

I have no major risk to raise.

Minor issues/risks:

I noticed the point made in the data analysis section about transcripts planned to be fully anonymised. I understand the concern, as few interviews – of perhaps just 5 per site – might well render participants easily identifiable. However, I wonder if this is desirable for the analysis process where clearly data from different sites and between job roles might be worth comparing. Perhaps one round of 'sufficient anonymising' could be undertaken at the transcription stage; and then a further step to take out more identifiers later on to make sure quotes in dissemination and if data might be shared would not identify any participants.

Signed:

(Electronic signature required)

Date: 6 December 2022

College of Medicine and Health Research Ethics Committee

Peer Review Form

Name of Reviewer:	Rosemary Simmonds
Employing Organisation:	University of Exeter
Qualifications and area of expertise (needs to be an expert in the methods to be used or proposed topic for this project):	BSc Applied Psychology & Sociology MSc Social Research Methods I have18 years' experience of conducting qualitative health research using interviews and observation/ethnographic methods etc. I am also currently working on a qualitative study as part of a trial of a new stroke pathway for thrombectomy treatment.
Details of any potential conflict of interest:	None
Name of Researcher:	Keira Pratt-Boyden / Julia Frost
Project Title:	Stroke Audit Machine Learning SAMueL 2 Qualitative Study

What is your overall assessment of the quality of the study? Is there a clear research question/aim? Are the methods of data collection appropriate and adequately described? Are the methods of data analysis appropriate and adequately described?

Major points: The study appears to be well conceived and demonstrates sensitivity to the research context, participants and patients. Research aims and objectives are clearly stated.

Minor points:

Should the primary research question in (4. Research Aims and Questions) also be included in the Protocol Summary?

What specific improvements would you like to see the applicant make in relation to the quality of the study?.

Major improvements:

Just a bit worried by the amount of data collection planned in a short space of time – would it be possible to simplify/shorten each work package to allow for unforeseen hold ups and to allow more time for data analysis?

I found the section in Work Package 1, a bit confusing from: "These questions will enable us to understand the personal, social and institutional contexts around thrombolysis..." The questions in the section above are clear but it is not easy to see how they link with the questions in the section below on Organisational culture, Decision pathways and Personal perspectives. Would it be possible to make these links clearer and simplify the questions posed in the three aspects of context? Are there some concepts in implementation frameworks around Context that could be used to frame some of these questions?

As observation is the main data collection method, I think more description/explanation is needed of how the observation protocol is used, data extracted, managed and analysed.

Minor improvements:

What is your opinion of the originality, reliability and importance of the study?

I thought this was a very interesting, exciting, and innovative study that builds upon published literature and previous studies. The main research questions are clear, and the methods are appropriate - though the time frame is very tight and could impact on the quality of the study findings if not enough time is left for analysis. This is an important study that could add value to healthcare and stroke care in particular.

Lastly, are there any potential ethical issues/risks you would like to bring to the attention of the Committee?

Major issues/risks:

None

Minor issues/risks:

None

Signed:

(Electronic signature required)

Rosemary Laura Simmonds

Date: 10 November 2022

Response to peer review

IRAS ID: 322303 Study Number Centre Number

Title of Project: **Stroke Audit Machine Learning (SAMueL-2)**

comments = C and responses = R

C: ...How the researcher will be guided in observing decision making, particularly as the researcher does not seem to have a clinical background

R: The wider SAMueL-2 team includes a clinical investigator (stroke consultant) as PI, along with other stroke professionals on the advisory boards. The NASSS framework in particular and qualitative protocol have been iteratively developed and refined with stroke professionals and wider health professionals. Besides being guided by NASSS, the researcher will use her experience and training of numerous years in health research. She will have fortnightly supervision style check-ins during observation with the rest of the qualitative team and will continue to refine her observation protocol throughout the periods of observation.

C: A brief added explanation in the protocol how the observation protocol will be used would be helpful.

R: This has now been added.

C: I noticed the point made in the data analysis section about transcripts planned to be fully anonymised. I understand the concern, as few interviews – of perhaps just 5 per site – might well render participants easily identifiable. However, I wonder if this is desirable for the analysis process where clearly data from different sites and between job roles might be worth comparing. Perhaps one round of 'sufficient anonymising' could be undertaken at the transcription stage; and then a further step to take out more identifiers later on to make sure quotes in dissemination and if data might be shared would not identify any participants.

R: For 'sufficient anonymising' we will use the following anonymisation formula: Specialist Registrar post Stroke Rotation Site A, then for publication Dr A, Site A.

C: Just a bit worried by the amount of data collection planned in a short space of time – would it be possible to simplify/shorten each work package to allow for unforeseen hold ups and to allow more time for data analysis?

R: This is an ambitious research project and as such, the work packages are intentionally broad and substantial, to allow for flexibility and contingency, (including hold ups) given the substantial difficulties facing research in the NHS currently.

C: I found the section in Work Package 1, a bit confusing from: "These questions will enable us to understand the personal, social and institutional contexts around thrombolysis..." The questions in the section above are clear but it is not easy to see how they link with the questions in the section below on Organisational culture, Decision pathways and Personal perspectives. Would it be possible to

make these links clearer and simplify the questions posed in the three aspects of context? Are there some concepts in implementation frameworks around Context that could be used to frame some of these questions?
&
C: I felt there was a slightly confusing mix of topics without topic guide questions and topics that were almost phrased as questions. I feel this could be improved by providing clear, user friendly topic guide questions with any probes bullet pointed underneath the questions.

R: Multiple questions have been included in both the protocol and the topic guides to give different examples according to the different sections, however some links have been added in the protocol for clarity. The topic guides have been slightly reformatted. The NASSS framework includes Context, so implementation frameworks are not necessary.

CURRICULUM VITAE

Name:	
Dr Keira Zoe Pratt-Boyden	
Present appointment: *(Job title, department, and organisation.)*	
Research Fellow, Department of Health and Community Sciences, University of Exeter Medical School, Faculty of Health and Life Sciences, University of Exeter	
Address: *(Full work address.)*	
Department of Health and Community Sciences, University of Exeter Medical School, Faculty of Health and Life Sciences, St Luke's Campus, Heavitree Road, Exeter, Devon, EX1 2LU	
Telephone number:	**Email address:**
(01392) 724086 **07913852501**	k.z.pratt-boyden@exeter.ac.uk
Qualifications:	
2012 MSc Social and Cultural Anthropology, University College London, Distinction 2022 Associate Fellowship Scheme, University of Kent 2022 PhD Anthropology, University of Kent, No Corrections	
Professional registration: *(Name of body, registration number and date of registration.)*	
N/A	
Previous and other appointments: *(Include previous appointments in the last 5 years and other current appointments.)*	
Previous appointments: 2020-2022 Research Assistant, SOAS University of London, Department of Anthropology and Sociology, The Anthropology of Peer-Supported Open Dialogue Project, PI Prof David Mosse 2022 Research Associate, The University of Kent, Department of Sociology, Social Policy	

and Social Science Research, The Big Local Project, PI Dr Dawn Lyons

2017-2020 Graduate Teaching Assistant, The University of Kent, Department of Anthropology and Conservation

2016-2018 Research Associate, University of Sussex, Department of Health and Social Care, (various projects) including Using Digital Genograms with Children, and Improving Access to South Downs Community Park for Vulnerable people

2015-2016 Research Assistant (Ann McPherson Fellowship), The University of Oxford, The Medical Sociology and Health Experiences Research Group (various projects and training in qualitative health research, including Improving Young People's Access to GP for Mental Health, Skin Conditions, Experiences of Psychosis and Improving PPI in Surgical Trials

2015 Research Assistant, The University of Oxford, Centre for Migration, Policy and Society, The Experience of Homelessness and Begging in the UK, PI Bridget Anderson

Research experience: *(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)*

Prior to my PhD I have worked as a research assistant and associate across multiple universities and NGOs for 14 years, specialising in improving patient health experiences, and access to primary care. I have specialised in qualitative health research since 2015, when I completed a qualitative research pre-doctoral fellowship. This fellowship including extensive training and development in qualitative methods, as well as experience across methods (interviews, focus groups and observation) and methodologies (trainings in different analyses, including interpretive phenomenological analysis and analysing ethnographic data). I have conducted research with and have training in researching with different vulnerable groups, including homeless populations and people with severe mental distress. I have worked with various stakeholders in health to improve primary healthcare, including GPs, Psychiatrists and Health commissioners.

Research training: *(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)*

GCP, The University of Exeter, 2022

The Ethical Researcher, Using Creative Methods, Keeping up to date with Literature

Creative Methods and Multimodal Ethnography, Goldsmiths University, 2017

Secondary Trauma in Research, University of Oxford, 2016

Qualitative methods training: Qualitative Research Methods, How to Conduct Literature Reviews, Introduction to Focus Groups, Filming Qualitative Interviews, The University of Oxford, 2016

Qualitative Interviews, University of Oxford, 2015

Relevant publications: *(Give references to all publications in the last two years plus other publications relevant to the current application.)*

Mosse, D., Baker, D., Carroll, M., Chase, L., Kloocke, R., Wickemasinghe, K., Cramer, B., Pratt-Boyden, K., Wuerth, M. *Forthcoming*, The Contribution of Anthropology to the Study of Open Dialogue: Ethnographic Research Methods and Opportunities, Psychology for Clinical Settings: *Frontiers in Psychology.*

Lyon, D., Tunåker, C., Pratt-Boyden, K. *Forthcoming*, Decision-Making among Local Neighbourhood Groups; The Case of 'Invisible Whispering'. *Social Anthropology.*

Sevasti-Nolas, M., Pratt-Boyden, K. *Forthcoming*, 'Felt Closeness: Mixed Methods Evaluation of an Interdisciplinary Innovation Project: from Analogue to Digital Ecomaps for Child Social Work Practice', *Social Work Practice*.

Lyon, D., Tunåker, C., Pratt-Boyden, K. and Theodossopoulos, D. (2021) *Power in Big Local Partnerships*. Local Trust.

Armstrong N, Pratt-Boyden K. (2021) Silver Linings: how Mental Health Activists can help us Navigate Wicked Problems. *BJPsych Bulletin*. 45(4):227-230.

Sevasti-Nolas, S., Pratt-Boyden, K. and Watters, C. (2020) 'The Role of Place and Mobility in Refugee Systems of Social Support'. *International Journal of Migration, Health and Social Care*. 16(4): 333-348.

Crocker, J.C., Pratt-Boyden, K., Hislop, J. Rees S., Locock L., Petit-Zeman S., Chant A., Treweek S., Cook J., Farrar N., Woolfall K., Bostock J., Bowman L., Bulbulia R. (2019) Patient and Public Involvement (PPI) in UK surgical trials: a survey and focus groups with stakeholders to identify practices, views, and experiences. *Trials* 20, 119.

Signature:	**Date:**
Keira Pratt-Boyden	13/12/2022
