Development and implementation of Realistic Medicine for severe stroke through Shared Decision Making at The Royal Infirmary of Edinburgh (RIE)

Short title: ShareStrokeDecisions

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LIST OF ABBREVIATIONS

ACCORD	Academic and Clinical Central Office for Research & Development - Joint office for The University of Edinburgh and Lothian Health Board
CI	Chief Investigator
CRF	Case Report Form
DORIS	Data base of research in stroke
ED	Emergency Department
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
NG	Nasogastric tube
PEG	Percutaneous endoscopic gastrostomy
PI	Principal Investigator
QA	Quality Assurance
REC	Research Ethics Committee
RIE	Royal Infirmary of Edinburgh
SOP	Standard Operating Procedure
SDM	Shared decision making

1 INTRODUCTION

1.1 BACKGROUND

The burden of stroke disease

Worldwide, stroke is the second leading cause of death, the third leading cause of disability and results in 6.5 million years being lived with disability. There are over 100,000 new strokes in the UK each year, and stroke incidence is predicted to rise by around a third by 2035. Each year, almost a thousand people are admitted to Royal Infirmary of Edinburgh (RIE) with acute stroke. Up to 500 of these strokes are severe; at 6 months, case fatality is almost 30%, and 80% of survivors have severe disability.

Approach to management of life threatening stroke

Stroke occurs suddenly, and so patients and families are often unprepared for making treatment decisions. For most people, a stroke is a shock. With no prior experience of dealing with stroke they are not only unprepared; also they just don't know what options they have nor do they have a benchmark for supporting them to make the best decisions for themselves or their loved one.

Furthermore, aphasia, cognitive impairment or impaired consciousness mean that patients cannot express their own views. So, active treatment is often given to 'see how things go', but this can prolong dying, cause discomfort and harm, and lead to unwelcome survival with severe disability and lifelong institutional care, which might be inconsistent with the patient's prior wishes.

Our previous work in this area

We have previously performed five pieces of research in this area, and one audit.

a) Longitudinal qualitative study of people with severe stroke, their carers and health care professionals from three hospitals in Scotland [1]. The 99 interviews showed that health care professionals were over optimistic about prognosis in the acute phase, so that families would be provided with hope. However, although some families wanted hope; others wanted to hear 'the truth' (even if this was likely death or survival with severe disability), meaning that futile or invasive treatments could be avoided. Families often start grieving in the early stage before a patient has died. This grief was anticipatory and also related to loss of the person's previous life and abilities. Yet bereavement support was not routinely provided by stroke services.

b) We performed a survey of 599 health care professionals to inform the development of our on-line educational materials. We found that communication of uncertainty was difficult, that family members often had different views about how intensive acute stroke care should be, and that eliciting patient's views was often difficult because of aphasia and cognitive impairment [2].

c) We developed online training to help health care professionals have sensitive conversations about difficult treatment decisions. This was funded by the Scottish Government. It is now available free through the Chest Heart & Stroke STARS training modules. It has been accessed by over 1000 health care professionals, mostly nursing staff.

d) At RIE, we performed a longitudinal cohort study of 403 patients with severe stroke, to validate prognostic models for important functional outcomes including speech, swallowing, anxiety or depression, mobility and living at home that we had developed form large trial data sets. Our models, though require further evaluation, could predict recovery of specific abilities after stroke with reasonable accuracy [3,4].

Longitudinal qualitative research identified that patients often wanted hope in the early stage even if prognosis was poor, but retrospectively wished that they had been given realistic information to help prepare for the consequences of stroke. Families were involved in decision making but needed information and support to guide these difficult decisions [5,6].

e) We performed a Chief Scientist Office funded Delphi survey to identify the palliative care outcomes considered most important for future research by health care professionals, stroke survivors and stroke support organisations. Shared decision making (SDM) was the top priority for future research [7]. We held a stakeholder meeting on 4th March 2020; seven of the Delphi respondents attended and around 20 other staff involved in stroke care, one bereaved carer and one stroke survivor. Consensus was reached that SDM was a priority for future research.

f) We searched DORIS (database of research in stroke) (www.askdoris.org, accessed 23.2.20) as part of a systematic review on palliative care after stroke for publications about SDM after severe stroke. There are four citations - all to different sections of the Canadian Stroke Guidelines which state that SDM should be used to plan rehabilitation and discharge. There is one study of SDM in relation to thrombolysis in acute stroke [8] using a computerised decision aid which was found to be feasible and acceptable. A review article in 2017 of SDM in stroke identified decision making aids for anticoagulation for atrial fibrillation [9]. Our searches for ongoing trials in palliative care after stroke identified two trials in the broad area of decision making: (Team-based Versus Primary Care Clinician-led Advance Care Planning in Practice-based Research Networks (https://ClinicalTrials.gov/show/NCT03577002 201) which includes stroke patients and a decision Aid Feasibility Trial for Families of Critically Ill Stroke Patients https://ClinicalTrials.gov/show/NCT04143113 2020).

g) Audit. A BSc medical student, Gemma Woodhead, audited documentation of communication with families and patients, in 40 consecutive people who died from stroke at RIE at the end of 2019 and beginning of 2020. The audit tool, designed for specifically for this audit, was based on the General Medical Council guidelines for the care of the dying patient. The median number of family meetings was 2 per day, the hospital team generally discussed clinical condition and management of patients, but did not provide emotional support or information about death. This audit is consistent with the findings of our qualitative study [1], in which families and patients reported the need for more emotional support and bereavement support.

<u>The need to improve the process of making decisions about care after severe stroke</u>
These pieces of work described above have demonstrated the need to improve the process of making decisions about care. This Quality improvement project which has been funded by Edinburgh and Lothian Health Foundations, aims to improve quality

of decision making after severe stroke, utilising shared decision making, which will incorporate Tailored Talks.

What is Shared Decision Making (SDM)?

The American Heart and Stroke Association advocates SDM after stroke, but there is no guidance about what how to do this in practice or whether this improves either the process of care or patient/carer outcomes [10].

Shared decision making (SDM) can be defined as an interpersonal, interdependent process in which health professionals, patients and their caregivers relate to and influence each other as they Collaborate in making decisions about a patient's health. Policy makers perceive SDM as desirable [11] because: a) patient involvement is accepted as a right [12]; b) patients in general want more information about their health condition and prefer to take an active role in decisions about their health [13, 14] c) SDM may reduce the overuse of options not clearly associated with benefits for all and increase the use of options clearly associated with benefits for the vast majority of the concerned population [15] (d) SDM may reduce unwarranted healthcare practice variations([16]); and e) SDM may foster the sustainability of the healthcare system by increasing patient ownership of their own health care.[17].

SDM depends on knowing and understanding the best available evidence about the risks and benefits across all available options while ensuring that the patient's values and preferences are taken into account [18-20]). A model of SDM, developed following a systematic review, identified nine essential elements to the SDM process [21]). Although this model was not developed specifically for stroke-these principles are all applicable in severe stroke.

- define and explain the healthcare problem,
- present options,
- discuss pros and cons (benefits, risks, costs),
- clarify patient's values and preferences,
- discuss patient's ability and self-efficacy,
- present what is known and make recommendations,
- check and clarify the patient's understanding,
- make or explicitly defer a decision, and
- arrange follow-up.

In another review article [22], six aspects of SDM were described: situation diagnosis, choice awareness, option clarification, discussion of harms and benefits, deliberation of patient preferences, and making the decision. These domains broadly overlap with the ones above. These two frameworks will be considered at the co-production workshops.

The NICE statement on SDM suggests that patients and doctors play complementary roles in the process, with doctors sharing expertise on diagnosis, disease aetiology,

prognosis, treatment options, outcome probabilities whilst patients bring expertise in experience of illness, social circumstances, attitude to risk, values (what matters to them) and preferences.

Components of a Shared Decision making process

There are three broad categories of SDM interventions: 1) interventions targeting patients (e.g. a decision aid such as a pamphlet), 2) interventions targeting healthcare professionals (training) and 3) interventions targeting both.

A Cochrane review identified 87 studies of interventions for SDM by health care professionals (44 studies looked at activities for patients only, 28 studies looked at activities for both healthcare professionals and patients, and 15 studies looked at activities for healthcare professionals only) [23]. Outcomes included the use of SDM (measured by observation or by patient reported outcomes), patient outcomes (including affective/cognitive outcomes, behavioural outcomes, health outcomes) and process outcomes (e.g. time, cost). There were no studies in stroke. Despite the large number of trials, the reviewers were unable to draw any conclusions about the effectiveness of any of the approaches. In a commentary on this review, Professor Richard Lehman (Professor of the Shared Understanding of Medicine in the Institute of Applied Health Research at the University of Birmingham) stated 'For clinicians to share decisions effectively, they also need a different attitude towards their role, they need a new set of skills, they need better and more adaptable tools, and they need to be provided with the structures and the environment where real personal communication and sharing become possible' (https://www.evidentlycochrane.net/shared-decision-making-essential-but-hard-to-measure/ accessed 26.2.20).This is the aspiration for this project of SDM in severe stroke.

We believe that any intervention for use in acute severe stroke needs to meet the needs of patients, family and staff, rather than just one or two of these groups. This is based on our qualitative research (in which families often stated that they wished that they had had more information about likely outcomes in the initial stages of stroke [1], our survey of health care professionals identified that communication of likely outcomes and dealing with uncertainty was an area where further training was needed [3] and our further qualitative interviews with patients and families [6,7].

Theoretical models underpinning Shared decision making

The Cochrane review identified several theoretical models underpinning the SDM intervention. Although complex interventions should, in general, include theoretical models to underpin them, there is no consensus in the literature about how to do this for SDM [24]. Furthermore, most complex interventions with people and families near the time of death do not conform to any theoretical framework, and have no outcomes that can be truthfully or usefully measured within the structure of a time-limited trial. Thus, we will consider theoretical models in our co-production workshops but will not be constrained by any particular model.

How might shared decision making influence outcomes after severe stroke?

Some authors have shown that communication between healthcare professionals and patients, including SDM, can lead to improved health outcomes in direct but also

in indirect ways [25]. Thus, according to an adapted conceptual framework linking clinician-patient communication to health outcomes, SDM can have an impact on affective-cognitive outcomes (e.g. knowledge, understanding, satisfaction, trust), behavioural outcomes (treatment decisions, adherence to recommended treatments and adoption of health behaviours), as well as health outcomes (e.g. quality of life, self-rated health and biological measures of health) [26]). After severe stroke, it is plausible that SDM may lead to an increase in the proportion of people dying, reduce the proportion living with severe disability and reduce the number who have NG/NG/PEG tubes inserted. Thus, for any new process of SDM that we wish to implement in practice, measuring these variables is of relevance, and so in this project we will use routinely collected audit data from the Scottish Stroke Care Audit (SSCA) to explore the association between SDM implementation and these process outcomes.

Shared decision making and its relevance in severe stroke

At our stakeholder event in March 2020, which concluded our CSO project to identify core outcomes for a future trial of palliative care in stroke, it was agreed that the following outcomes were also of importance to families and patients: time to death, length of stay in hospital, number of moves between different areas of the hospital, the use of NG/NG/PEG tubes, and whether families and patient achieve their preferred outcome (whether this is living with severe disability or dying).

In our own clinical experience, medical staff take different approaches to SDM and meetings with families and patients to discuss treatment options. Sometimes meetings are led by senior doctors, and sometimes delegated to junior doctors, the amount of information that is provided varies substantially, and documentation of discussion is also highly variable. This variation is a reflection of the complexity of decision making, and uncertainty amongst physicians about how much, and which, information to provide to patients and their families. Sometimes discussions about dying are difficult-particularly in patients who had previously been fit and well, and doctors often want to provide hope even though prognosis is poor [5,6].

There is a need for support for health care professionals and families to make decisions that are in keeping with the wishes, values and beliefs of patients who have a severe stroke. Whilst it is often the medical and nursing staff who have these conversations, rehabilitation staff have told us about the lack of training for using rehabilitation to support a comfortable death. The general perception of rehabilitation is that it is ‘to get people back on their feet’, but therapists can also play a role in making patients more comfortable. Thus, the rehabilitation team needs to be involved in SDM.

Decisions might include being allowed to die comfortably in the acute phase of stroke rather than survive with unwelcome severe disability, and avoid unpleasant and invasive treatments that have little or no prospect of altering the final outcome. Sometimes the possibility of dying peacefully and without discomfort can be missed if active treatment is commenced with the aim of ‘seeing how things go’. Furthermore, our audit of dying after stroke suggests that the health care team need to consider how to provide emotional support and also be empowered to discuss death more openly, rather than just choices about treatment approaches.

General Medical Council: end of life care guidance and shared decision making

The General Medical Council (GMC) has written extensive guidance about the approach that doctors should take to making decisions about end of life care, but applying this generic guidance in practice in stroke is challenging because of the common clinical features of severe stroke (sudden onset, uncertain prognosis, aphasia, dysphagia), and because some potentially unpleasant treatments (e.g. artificial tube feeding, intermittent pneumatic compression for deep venous thrombosis prevention) lead to an increase in the proportion of patients surviving with severe disability. Furthermore, decisions about active treatment or not often have to be made very quickly. We have developed an audit tool based on these GMC guidelines; and then audited consecutive deaths in 2019 (Gemma Woodhead, BSc student). We demonstrated that there are generally multiple conversations with families in people who die from stroke, but the content of these discussions is highly variable and often not structured in a standardised manner.

1.2 RATIONALE FOR THIS STUDY

The need for information targeted at the individual and specific needs of patients and families

There is already a lot of factual information available about stroke for patients and families, but this is not generally tailored towards the needs of individual patients. This may explain why general 'information provision' as an intervention tends not to improve outcomes [27]. Families and patients need is information tailored towards their own needs and about their own specific stroke-related problems. At our stakeholder workshop on 4th March 2020, a stroke survivor Mr Neil Francis told us how important it is to provide stroke survivors and families information that is relevant to them as individuals rather than generic information. For example, a patient with cognitive problems after stroke as the only residual symptom does not require extensive information about other post-stroke problems. Mrs Lorna Tweedie, a bereaved carer, told us how she would have valued honest and realistic information about likely prognosis of her father, and this might have avoided distressing treatments with little or no chance of success. Professor Martin Dennis has developed Tailored Talks, a digital presentation platform which facilitates the tailoring, structuring and sharing of relevant information with patients and families. It includes a series of powerpoint slides about stroke, its effect and treatment. Chest Heart & Stroke Scotland has been involved in its development. A clinician can select relevant slides and use them as a basis for discussion; the slides can also be emailed to patients and families after the discussion, and a list of the slides provided can be documented on TRAK care. The principle of providing only the information that is relevant to specific patients and their families, at a time when the information is relevant, is at the heart of 'Tailored Talks'.

Tailored Talks have been piloted by Dr Visvanathan at RIE and feedback from families was positive; they have been made available to the consultant stroke physicians at the end of 2020; any views of staff as they start to use these talks will be discussed during the co-production workshops. A short demonstrator video can be seen at https://www.pogo-studio.com/digital-healthcare/

The need to establish views and values of patients and families

Provision of information is a component of SDM, but information on its own, even if it tailored towards the need of individual patients, is not enough. Equally important is the ability of medical staff to empower families and patients to make decisions-and to redress the power balance that currently exists with doctors and nurses having the skills and knowledge, whereas families and patients do not have the same level of knowledge. This includes the ability to ask patients and families questions in a sensitive way that elicits patients' views about deeply personal issues such as attitude towards death. Empathy is crucial: the ability to listen, take on board prior views of the patient, to understand the values and priorities of patients, and to integrate this is key to discussions and SDM. Also, it is crucial to ensure that families are not left 'feeling guilty' and having decisional regret if they are involved in a decision to allow a person to die; provision of a structured process may help to mitigate this. These important aspects of SDM will be explored in the co-production workshops.

Furthermore, our audit of TRAK care demonstrated that provision of emotional support, and information about dying, tends not to be addressed by the health care team. Thus, we will need to ensure that Tailored Talks includes information about the emotional effects of severe stroke, the dying process, and what happens after death. Close working between members of the multidisciplinary stroke team is crucial; and sharing information between the team about the patient's and families about their hopes and desires is very important in advance of these difficult discussions with families.

Overview of this study

This protocol covers the 15 month period of data collection. Data will be analysed and disseminated after data collection is complete.

a) Development of SDM process through co-production (months 0-6) and its implementation into clinical practice at RIE (months 6-12)
b) Audit of process of care, death, discharge destination (months 6-12).
c) Research: to explore views on SDM process (months 3-9) and to collect data on outcome 6 months after stroke (months 9 to 15).

2 STUDY OBJECTIVES

2.1 OBJECTIVES

2.1.1 Primary Objective

The primary objective of this project is to develop and embed a process for Shared Decision Making (SDM) for severe stroke into the stroke service at Royal Infirmary, Edinburgh, starting at the point of admission to RIE, in either Medical Assessment Unit or the Emergency Department (ED). This process will incorporate Tailored Talks. The goal of the SDM process is to enable staff to be empowered and confident to have difficult conversations with patients and families, including the communication of poor prognosis and uncertainty, and enabling patients and carers to be more effectively able to participate in these conversations. This should ensure that

treatment decisions are more aligned with patient's values and beliefs. The SDM process will be developed through co-production.

2.1.2 Secondary Objectives

The second objectives are to

a) Evaluate how well the SDM process is implemented into practice (through a 'sprint' audit of the use of Tailored Talks at RIE, utilising the existing Scottish Stroke Care Audit (SSCA))

b) Explore whether implementation of the SDM is associated with changes in clinical processes and outcomes (death, institutional care, discharge to another hospital, use of feeding tubes), through a 'sprint' audit in the SSCA, before and after implementation of SDM.

c) Obtain data on patient/families/staff views of the SDM process (through quantitative and qualitative research)

d) Explore whether patients/families' preferred outcome matches the actual outcome at 6 months (through quantitative research).

2.2 ENDPOINTS

2.2.1 Primary endpoint

This primary end point is to understand if it is possible to embed shared decision making into clinical care within the stroke service at the RIE. We will report in detail the process that was developed through co-production workshop, and how it was embedded into the RIE stroke service, in sufficient detail to allow others to replicate the process. We will use the TIDIER checklist as a guide to documentation [33].

2.2.2 Secondary endpoints

a) Evaluate how well the SDM process is implemented into practice (through a 'sprint' audit of the use of Tailored Talks in the Scottish Stroke Care Audit (SSCA)). We will extract data on how often Tailored Talks are recorded in each person's clinical record on TRAK, between months 0 and 12 of the project.

b) Explore how implementation of the SDM relates to clinical outcomes (death, institutional care, discharge to another hospital, use of feeding tubes), through a 'sprint' audit in the SSCA, before and after implementation of SDM). We will plot these outcomes on a monthly basis, over the one year period of this sprint audit.

c) Data on patient/families/staff views of the SDM process; through quantitative research (SURE and CollaboRATE questionnaires) and qualitative research (interviews).

d) Do patients/families' preferred outcome at the time of stroke match the actual outcome at 6 months? Preferred outcomes are a) death b) discharge home for palliative care and c) long term disability in a nursing home. This will be done through quantitative research.

3 STUDY DESIGN

There are there elements to this study; coproduction, audit and research.

a) Development of SDM process through co-production (months 0-6) and its implementation into clinical practice at RIE (months 6-12)
b) Audit of process of care, death, discharge destination (months 0-12) before and after implementation of SDM process.
c) Research to explore patient, relative and staff views on SDM process (months 3-18)

Coproduction:

Overview of the co-production process

We will collate, synthesise and disseminate the multiple perspectives about SDM after severe stroke from our previous research and other relevant literature (e.g. Cochrane review of interventions to increase SDM). As part of this process, we will develop a logic model specifying key elements of the proposed intervention such as mechanisms of action, approach to implementation, mediators, and expected outcomes. We will develop a SDM process and supporting materials. The supporting materials will include slides from Tailored Talks. Some important topics are not currently included in Tailored Talks; these include information about death/dying after stroke, emotional problems, and bereavement after stroke. The use of SDM in practice will require staff training. We will, as part of the co-production, develop training for staff. In the future, we hope to be able to report the number of staff in Scotland who have been trained and therefore upskilled. In the longer term, these materials could be integrated into medical training programme.

Co-production methods

Using co-production methods, in which existing service users (bereaved carers and stroke survivors), and older lay people, who have not yet had a stroke, and service providers play an equal role. We will develop the structured SDM process to help families and staff make decisions in keeping with patients' values and any prior expressed views. We will convene four co-production workshops over a six month period. These will be preceded by an initial meeting (Summer 2021) to outline the

process and explain to all participants what is required of them, including the time commitment. The group will include a minimum of 10 people and a maximum of 16 people. The group will include a mix of health care professionals (doctors, nurses, physiotherapists, occupational therapist and speech and language therapist) stroke survivors and bereaved carers. The group will be facilitated by an experienced research fellow, Dr Sarah Morton, and the lead stroke research nurse, Mr Allan Macraild.

The SDM process is likely to commence in Emergency department, where discussions are initiated with patients and families, and where decisions about hyperacute treatments are made. The SDM process will continue into the inpatient stroke service, and discharge planning (if patients survive). We will draw on existing knowledge of SDM from the Cochrane review, our own research, and our audit of documentation of discussions with families performed by a BSc medical student for 40 deaths occurring on the integrated stroke unit at RIE in 2019/2020.

There has been an increased focus on using co-production as a method to help develop and shape services, and especially for those which are complex in nature and where there are multiple pathways. Co-production approaches involve service users in designing and, in some cases, delivering services in equal partnership with service providers. This process recognises and utilises the knowledge and lived experiences of service users and providers. Healthcare professionals' expertise is primarily based on the knowledge of the condition, such as outcome, aetiology, treatment pathways, diagnosis and prognosis. For stroke survivors and caregivers, their knowledge is more related to the impact and burden of the condition on daily life, the 'shock' of stroke, and the treatment dilemmas that they are faced with, without any preparation. In addition, attitudes, values, perceptions and knowledge of likely facilitators and barriers to implementing behaviour change recommendations are important-this applies to behaviour change amongst the staff who will be involved in SDM process. All participants in the co-production work will bring important knowledge and experience to the co-production activities.

Adapting co-production to Covid 19 pandemic

There is no single or best approach to achieve co-production outcomes; however, the process is iterative and cyclical, it focuses on formulating, prototyping, piloting and evaluating interventions or methods of change. Ideally, stakeholders would meet regularly, face to face, over a defined period in facilitated co-production groups, but due to the Covid 19 pandemic, we will explore other ways to facilitate groups; this is probably include on-line groups using Microsoft Teams, supplemented by telephone conversations and face-to-face meetings if possible. We cannot decide for certain what our approach will be as we need to remain responsive and flexible according to the ongoing course of the Covid 19 pandemic. There are some benefits of using on-line co-production workshops including saving travelling time, the 'chat' function if people want to add comments during the discussion, and also the opportunity to turn off the video if a participant becomes upset. Also it can allow later capture of information and reviewing of the discussions.

Co-production group members will work collaboratively in a structured and facilitated way to discuss and build on ideas, develop a process and establish implementation plans for improving SDM. This may include preparatory or additional development work occurring outside of the regular group meetings, and discussion with other relevant stakeholders. For example, if Stroke Association Scotland is involved, the representative may consult with stroke survivors through their support groups and

relevant professionals. Work occurring outside of the planned meeting will be negotiated and agreed with individual group members.

The evidence generated from our previous research will be presented in an accessible format to co-production group members. We want the groups to progress from understanding '*what is going on now*', to '*what we want to happen in future*' (the intervention) and '*how we will deliver*' this (implementation planning).

Preparatory meetings: rationale and practicalities

Prior to establishing the co-production groups, the researcher will facilitate exploratory and preparatory meetings at RIE (or via Microsoft teams, or by telephone). One meeting will be with service providers/professionals, and the other with stroke survivors and caregivers. The purpose of these initial meetings is to provide an opportunity to explore and develop an understanding of the co-production process, to establish whether individuals can commit to sustained engagement with the process, to encourage the individuals to think about ways of working collaboratively, on an equal basis, and to introduce the concepts of shared decision making. Health professionals from Royal Infirmary inpatient service (including ED, acute medicine and the integrated stroke units) stroke survivors and caregivers, and older lay people who have not previously experienced a stroke will be recruited to the lay group. These meetings of the co-production groups will be facilitated by a research fellow. Recruitment of co-production members is described in more detail below.

Pre-meeting key objectives	Approach
• Provide an introduction to SDM and its potential importance in severe stroke (including the impact of severe stroke and treatment dilemmas) • Provide an opportunity for group members to explore and develop an understanding of co-production and what participation in co-production groups would involve. • Explore ways of working collaboratively on an equal basis with all co-production group members.	• Expert video presentations (5 minutes x2) • Facilitated discussion about the role and application of SDM in stroke

Co-production Workshops

Four workshops will be convened, likely between May 2021 to September 2021. These will be held once a month in the first week of each month. Each workshop is expected to last for approximately two hours – regular breaks will be provided, including for online workshops. Breakout rooms will be available for smaller group discussions.

The session objectives may evolve slightly over time, but the main topics are likely to be:

a) What happens now; what is good about what happens now; what is not so good and what needs improvement?
b) Review of information in Tailored Talks to identify what is particularly relevant to severe stroke, and to discuss how to implement the Tailored talks in practice
c) How to elicit patient and family views and values, as part of the SDM process. A checklist of questions that health care professionals might ask families could be the outcome.
d) How to implement the new SDM process into practice-using principles of quality improvement.

The groups will develop prototype resources (e.g. checklists for medical staff when having conversations with patients and families after acute stroke). Prototyping is used as a method for gaining feedback and refining the design of an intervention; it helps to identify potential issues with acceptability, utility, usability, and barriers that can be addressed prior to feasibility testing of the intervention. To achieve this, each of the co-production workshops will be delivered in three 'sections':

(i) to inform the group about relevant research and existing materials for each of the workshop topics;
(ii) to utilise the knowledge and experience of group members, this will normally take the form of conducting a series of activities using co-production materials specifically selected and/or designed for use during these co-production workshops. The exact format/content of each of the materials will be refined on an iterative basis ahead of each co-production workshop and will look to validate and build on findings from the previous workshop(s), and;
(iii) to evaluate the process of co-production. This section of the co-production workshop will, in the early workshops (1 and 2) utilise verbal summaries, feedback and questions, and in the later workshops (3 and 4) utilise a process of validation of user needs (by email following workshop 2) and validation of user requirements (workshop 3).

Summary of co-production workshops

Workshop number	What currently happens in SDM in severe stroke? What is good about the current process? What could be improved? What does current research tell us?
1 Overview of	INFORM

aims of the co-production	• Introductions • Discuss co-production workshp(s) aims and timeline, and agreement on how the group(s) can work effectively. • Reminder of the aims of the project as a whole and the specific focus of including what SDM is. • Presentation of evidence from our previous research. Sharing existing on-line materials that are used to support SDM • Presentation of evidence from our audit of documentation of the process of SDM.
	KNOWLEDGE
	• Carry out 'character profile' and 'character journey' activities to gather knowledge about who the users of the intervention will be and what is important to them. • Carry out 'asset mapping' activity to gather knowledge about what the group members already do to facilitate SDM after severe stroke • Work out what training for staff might be needed
	EVALUATE
	• Summary of workshop led by facilitator with group members invited to contribute (including feedback and questions), outline next steps and date of next meeting.
2 Designing a SDM tool-information for families and patients which includes information about stroke contained in 'Tailored Talks'	INFORM
	• Reflections and discussion of key points identified following workshop 1. • Presentation of relevant Tailored Talks materials. • Prediction of recovery of 'specific abilities' • Identify how to improve/change these materials
	KNOWLEDGE
	• Using persons derived from workshop 1 ('character profile' activity (1) and 'problems and solutions' identified by the research team from 'character journey'(2) and 'asset mapping' (3) activities ask participants to complete 'priority matrix' (4) worksheet • Complete 'opportunity card' (5) activity to allow group members to suggest their idea(s) for improving the Tailored Talks.
	EVALUATE
	• Summary of workshop lead by facilitator with group members invited to contribute (incl. feedback and questions), outline next steps and date of next meeting.
3. How can we	INFORM

elicit patient and family views, beliefs and values? Would a checklist of topics to be covered, be useful? How can we facilitate nurses, junior doctors and senior doctors to elicit such conversations? What training is needed?	• Presentation of evidence from our previous research including an audit of communication around the time of death on a stroke unit. • Reflections and discussion of key points identified following workshop 2
	KNOWLEDGE
	• Complete the 'solutions in practice' activity to establish how the SDM process could be introduced (by whom, when, where) and the supporting information required to enable stroke survivors to use the intervention independently, and supported by professionals (initially), caregivers and family/friends.
	EVALUATE
	• Summary of workshop lead by facilitator with group members invited to contribute (incl. feedback and questions), outline next steps and date of next meeting. • Agree timescale and responsibility of members and researchers for contribute to the development of prototype intervention materials.
4. How should we implement this intervention in clinical practice? What is 'quality improvement' and how do we use the QI principles to embed the process? If there is documentation, where should this be stored? Do we need implementation groups within ward settings to embed this new intervention?	INFORM
	• Review evidence related to effective implementation of SDM • Reflections and discussion of key points identified following workshop 3. • Agree responsibility of members and researchers for specifying how the intervention should be introduced and implemented and the supporting information required to enable staff to introduce the SDM intervention and engage with patient and family in discussion about treatment options.
	KNOWLEDGE
	• Review prototype intervention materials developed following workshop 3.
	EVALUATE
	• Participants to provide feedback on prototype materials. • Final revision of the prototype intervention, behaviour change strategies and implementation plan. • Recognition and celebration activity. • Summary of workshop lead by facilitator with group members invited to contribute (incl. feedback and questions), outline next steps.

<u>Underpinning principles of co-production</u>

We will consider the relevance of theory to underpin our work-though note that there is no single theoretical model that is widely accepted in SDM [24]. Co-production group members will be invited to consider different intervention functions (education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling, and enablement).

The co-production groups will also consider strategies based on the APEASE criteria, i.e. whether the intervention is: affordable, practical, likely to be effective and cost-effective, acceptable to all stakeholders (public, professional and managerial), likely to be associated with unwanted side effects or unintended detrimental consequences, and is it equitable (to what extent is the intervention likely to reduce or increase health inequalities, standard of living and wellbeing different samples of the target population).

Recording co-production meetings

Co-production meetings will be recorded-using Microsoft Teams (or audio-recorded if face to face). The researchers will prepare brief notes of the discussion and action points from each co-production meeting, will prepare agendas in consultation with the co-production group members, and write up detailed process notes after each session. In-between workshop sessions, the researcher will undertake a range of support activities including circulating meeting notes, preparing materials for the next workshop, undertaking tasks highlighted in the sessions alongside co-production group members, facilitating the prototyping activities.

A descriptive summary of demographic characteristics of the co-production participants will be reported. This will include age, gender, time since stroke (for the stroke survivors) and occupation. The audio recorded process records of the co-production group meetings will be transcribed using a secure and confidential transcription service. The transcripts will be anonymised in terms of participant identifiers. These data and those from researcher process notes recorded as part of the evaluation of each of the co-production workshops will be used to generate a summary of the process components and delivery mechanism

Safeguarding of adults:

It is possible that, during co-production workshops, stroke survivors or carers/family members may disclose information to the research fellows, or the research fellows may have concerns that the individual may be experiencing abuse, or is at risk of abuse. In such circumstances the researcher will follow Adult Safeguarding Policy for NHS Lothian in Scotland. The research fellows will discuss their concerns immediately with the Chief Investigator and if they are in agreement, the relevant persons will be contacted as soon as possible, this may be social services, their GP, or the community care team.

Potentially sensitive information:

Discussions within co-production workshops are very likely to cover topics that the stroke survivor, caregiver, health professional, public health professional or volunteer group members might find distressing. Participants will be made aware of this prior to consenting to take part. During the co-production workshops, it will be made clear that participants may pause, take a break and/or leave the session at any time. The researcher will advise on where stroke survivors and/or caregivers may seek further assistance where required, e.g. Patient Advice and Liaison Services, The Stroke Association (England) or Chest, Heart & Stroke Scotland. For other participants referral to line managers or staff support resources in their own organisations will be considered.

Risks, burdens and benefits:

Risks:
Participating in the study may bring back memories of difficult conversations at the time of stroke, or fear of dying and for relatives-memories of death of their loved one from stroke. The research team has experience of conducting co-production, observation and interview work with stroke survivors in stroke units and the community. A number of strategies can be employed should stroke survivors or caregivers or other co-production group members become distressed, these include: temporarily suspending or terminating involvement in the co-production workshop if that is the wish of the participant; referral to support services including the Stroke Association or Chest Heart & Stroke Scotland. In addition, referrals to community stroke service linked Stroke Specialist Nurses may be appropriate or the participant's general practitioner. For other participants referral to line managers or staff support resources in their own organisations will be considered.

Burden:
The time associated with participating in the study is recognised as a substantial commitment for all participants. Each co-production workshop will last approximately one hour thirty minutes, with regular breaks. Sessions will be block booked as to give participants plenty of time to make arrangements. We anticipate involvement will occur over a period of approximately six months for each participant. During this period there will be a maximum of five meetings for each participant to attend (4 workshops and one pre-meeting). Wherever possible we will seek to minimise any requests for participants to undertake independent activity outside of the co-production meetings.

Other than making available the time required to participate in the sessions, it is not anticipated that participants who are co-production group members would find participating in the study a particular burden. In our previous NIHR funded RECREATE study, participants in the co-production workshop indicated that they enjoyed and looked forward to the workshops – and especially appreciated the peer network they developed though them. Most were sad when the process ended.

Benefits:
Participating in the study would bring about no direct or immediate benefit to stroke survivors, caregivers, volunteers or health professionals/public health practitioners. However, the aim of the study is to develop an intervention to improve SDM after a severe stroke, therefore all participants would be making a contribution to these efforts to improve SDM. It is possible that as a consequence of participation in the co-production work and exposure to the evidence about severe stroke, that group members may learn more about their own stroke and rationale for decisions that had been made in relation to their own care.

Implementation of the SDM process.
The outcome will be a SDM process co-produced by health care professionals, stroke survivors, bereaved carers, which will then be embedded within RIE stroke service through quality improvement supported by NHS Lothian's Quality improvement facilitators. The project members will all play key roles in implementation-especially those with clinical responsibilities on the wards (Fergus Doubal and Richard O'Brien). The SDM process is likely to include a) individual prognostic information based on the characteristics of the stroke, including information in Tailored Talks b) training for staff c) a method to record SDM discussion in TRAK.

Audit:

Sprint audits will be performed to achieve the first two secondary objectives:

a) Evaluate how well the SDM process is implemented into practice (through a 'sprint' audit of the use of Tailored Talks in the Scottish Stroke Care Audit (SSCA))

b) Explore whether implementation of the SDM is associated with changes in clinical processes and outcomes (death, institutional care, discharge to another hospital, use of feeding tubes), before and after implementation of SDM).

The ongoing Scottish Stroke Care Audit (SSCA) at the Royal Infirmary already collects the following data: stroke characteristics, death (or not), time to death, duration of admission to the integrated stroke service, and discharge destination (another hospital, institutional care, home). TRAK care, from which the audit coordinator extracts these data, is automatically updated when a patient dies, even if this is after discharge from hospital.

From months 0-12, we will add the following additional fields to SSCA

a) National Institute of Health Stroke Scale score (NIHSS) on admission to hospital. We will define severe stroke as an NIHSS of at least 15.
b) How many times 'Tailored Talks' are documented on TRAK care? Tailored Talks will be an integral aspect of SDM process, and so this will capture implementation of the SDM process. This will be documented for all stroke patients, not just those with an NIHSS of 15 or above.
c) Feeding tube (nasogastric tube (NG) only, NG and Percutaneous endoscopic gastrostomy (NG/PEG); inserted at any point in their admission or not (yes/no) or neither.

Currently the SSCA coordinator at RIE receives a spreadsheet daily from the clinical team listing the patients admitted to the stroke service with acute stroke. Currently NIHSS is not assessed routinely, but from March 2021, clinical stroke nurses will assess NIHSS routinely in preparation for implementation of thrombectomy. For the purposes of this sprint audit, the SSCA coordinator will enter the NIHSS into SSCA data base.

The SSCA audit coordinator identifies and extracts relevant process data from TRAK care-at the time of their admission and when they are discharged (or die), and enter these additional data onto the SSCA database. Nasogastric /PEG tube insertion is always documented on TRAK; and so will be available to the audit coordinator to enter into the SSCA audit database as part of this 'sprint audit'.

The stroke research nurses, who are members of the clinical team, or the stroke outreach nurses, will receive a list of Chi numbers of patients admitted with stroke each day, will assess the mRS using the simplified short question version [28], and will document the mRS in the 'clinical notes' section of TRAK. The audit coordinator will then extract the mRS score from TRAK care and enter into the sprint audit fields on the SSCA database.

Between months 0-12 of this project, at monthly intervals, the SSCA coordinator will extract, in tabular form, for patients with an NIHSS of 15 or over, data on death (or not), time to death, duration of hospital admission, discharge destination (another hospital ward, institutional care or home), NG; NG and PEG tube insertion (or not) and the number of times Tailored Talks is documented. These data will be displayed using statistical process control charts (month by month) as we do for other aspects of process evaluation in SSCA. These data will enable us to explore whether the implementation of the SDM process (starting at month 6 has been associated with the proportion who die, time to death, NG/PEG tube insertion and discharge to institutional care.

Research:

Research will be performed to achieve the final two secondary objectives.

a) Obtain data on patient/families/staff views of the SDM process (through quantitative and qualitative research)

b) Explore whether patients/families' preferred outcome matches the actual outcome at 6 months (quantitative research).

Quantitative research

a) *Baseline questions*

Those who consent will be asked the following:

'If your (or your loved one's) stroke was so severe that you (they) could no longer look after themselves and require care in a nursing home, what would be preferable to you (or your loved one): Dying comfortably from the stroke in hospital'? 'Dying at home after a discharge for palliative care' or 'Surviving with disability but needing long-term care in a nursing home'.

'As you (or loved one) are now, would you prefer 'Dying comfortably from the stroke in hospital'? 'Dying at home after a discharge for palliative care' or 'Surviving with disability but needing long-term care in a nursing home'

The patient or next of kin will be asked to complete two questionnaires; the four item SURE test (https://www.england.nhs.uk/wp-content/uploads/2013/08/7sdm-report.pdf) [29] and the three item CollaboRATE tool (each item is scored on a five point Likert scale) [30]. Space for free text comments will be included

b) *2, 4 and 8 weeks*

The patient or family will be asked to complete the SURE test and the CollaboRATE tool. These time points have been selected as they are the likely time period during which discussions about key decisions are often had (e.g. hyperacute care, fluids, feeding tubes, 'Do not attempt cardiopulmonary resuscitation) 'escalation' to High Dependency Unit or Intensive Care Unit if the person deteriorates in the future, antibiotics or not for infection).

c) Six months after stroke onset

We will find out from SSCAS the actual outcome for these patients (death, discharge destination), and compare the actual outcome with the preferred outcome.

We will also perform telephone follow-up for all those patients still alive, to establish

a) mRS (0-6)
b) Specific abilities (Walk (yes/No); Talk (yes/no); Eat normally (yes/No); Live without major anxiety/depression (EQ5 5DL score). This will provide more detail about how closely the final outcome matches the preferred outcome. The actual outcomes will be cross tabulated with the preferred outcomes at admission.

Qualitative Research

a) Qualitative research with patients and relatives

Five qualitative interviews during the six month implementation period (months 6-12) with patients (if have capacity) and/or next of kin. The stroke research nurses will purposely sample so we have representation from different severity of stroke (at least one with a mrS 3, 4 or 5), requiring feeding tube (or not), age 70 or over and aged less than 70; severe significant premorbid illness prior to stroke. We will aim to recruit three patients (with capacity) and at two next of kins of patients without capacity.

Guided by a topic guide, we will ask about the SDM process, whether different clinicians provided apparently contradictory information, whether families were shown the brain scan (and if so was this helpful), whether the term 'palliative care' was used, did families and patients feel that they were treated as an individual, were preferences and values asked about and recorded, were they given the opportunity for further discussions and did they feel involved in the decision making process. We will use reflexive thematic analysis [31,32]; this provides flexibility of construction and interpretation, and is simpler than other methods such as grounded theory.

We accept that five interviews will not provide data saturation-we are constrained by the funding currently available and may seek additional funding to enable us to increase our sample size in order to achieve data saturation. However, five interviews will provide some valuable feedback about the process.

b) Qualitative research with staff

The experience of staff-and their views about embedding this SDM process into clinical care, will be evaluated through a focus group (month 13) just after the completion of the implementation phase. This will be convened by the lead stroke research nurse. We will include a mixture of ED, acute medicine and stroke unit nurses, doctors and allied health care professionals. We will aim to recruit 10 members. Analysis will be performed using reflexive thematic analysis.
We have chosen a focus group rather than individual interviews, as the discussion generated between the individuals reflects what happens in clinical practice, and is likely to be more revealing than individual interviews.

4. STUDY POPULATION

4.1 NUMBER OF PARTICPANTS

Co-production: we will recruit 10-16 people, aiming for 50% lay people and 50% professionals

Audit: All stroke patients included in the Scottish Stroke Care Audit at RIE who have an NIHSS of 15 or more during 0-12 months of the project, will have data extracted and plotted on statistical process charts. This will be around 400 patients.

Research: There are likely to be a total of 200 patients with severe stroke during months 3-9 of the study. We would expect a minimum of 100 to consent. Also, five patients/family members will be interviewed about the SDM process. Views of ten staff members will be obtained through a focus group after the end of the implementation phase.

4.2 INCLUSION CRITERIA

Co-production:

Stroke survivors will be eligible for co-production workshops provided they:

- Are aged 16 years or over
- Have experienced a severe stroke within the last 18 months and are either currently receiving stroke related care or treatment in community based services, or have previously received care or treatment from a participating stroke service
- Are able to attend RIE co-production workshops on line
- Are able and willing to provide written informed consent
- Are English-speaking and have access to email
- Are able to attend the dates of at least three of the five workshop sessions (i.e. four co-production workshops and one pre-meeting)
- Are able to use online packages e.g. Microsoft Teams

Caregivers will be eligible for co-production provided they:

- Are aged 16 years or over
- Are a family member/close friend of a stroke survivor who is either currently receiving stroke related care or treatment, or has previously received care or treatment from a participating stroke service; or bereaved in the past five years from stroke
- Are able and willing to provide written informed consent
- Are English-speaking and have access to email
- Are able to attend the dates of at least three of the five workshop sessions

At least one older lay person who has no experience of stroke, who has capacity, access to the internet and able to attend at least three of the five workshops.

- Are able and willing to provide written informed consent
- Are English-speaking and have access to email
- Are able to attend the dates of at least three of the five workshop sessions

Healthcare professionals will be eligible for co-production provided they:

- Are health care professional working in a stroke service in Scotland or in an A&E department, or in acute medicine and have regular contact with stroke patients-and are regularly involved in conversations to make shared decisions about severe stroke ('regularly' means at least once a month)
- Are able and willing to provide written informed consent
- Are English-speaking and have access to email
- Are able to attend the dates of at least three of the five workshop sessions

Research:

Patient and Relative:

- Patient (or next of kin/welfare guardian if patient does not have capacity) with severe stroke NIHSS of 15 or more
- Aged 16 or more
- Proficient in English

Staff: Staff will be eligible if they provide care in A&E, medical assessment or the integrated stroke unit at RIE, and are willing to provide informed consent.

4.2 EXCLUSION CRITERIA

There is no exclusion criterion.

5. PARTICIPANT SELECTION AND ENROLMENT

For the sprint audit in SSCAS, all patients admitted to RIE with stroke will be included.

5.1 IDENTIFYING PARTICPANTS

Co-production: The research team will seek suitable stroke survivors and carers through consultation with Stroke Association, Chest Heart & Stroke Scotland, from the Life after Stroke clinic at RIE, and also people who had participated in previous research projects and who had given consent to be contacted about further research that might be of interest to them. Additionally, a snowball sampling approach will be used, targeting additional participants with particular expertise/skills or based on recommendations at different stages.

We will seek a suitable older lay person through contacts in organisation such as Age Scotland, and the University of Edinburgh's Advanced Care Research Centre. We will ask these two organisations to identify a person whom we can then contact either by telephone or by post with a Participant Information leaflet and a Consent form.

In consultation with service managers, we will identify a range of professionals from different backgrounds (nursing, medical, allied health) and a range of seniorities.

Audit : All patients admitted to RIE with acute stroke are already routinely included in the Scottish Stroke Care Audit, for service evaluation purposes. The audit coordinator will provide us data on a month to month basis, anonymised, between months 0-12. Thus individual consent is not needed.

Research:

Patient and relative: We will invite all patients with an acute severe stroke (defined as an NIHSS of 15 or more at stroke onset) and their families admitted to RIE during months 3 – 9 to participate in the research aspect of this study. Potential participants will be identified by stroke research nurses, who are part of the clinical team, in collaboration with the ward staff. For patients with capacity, both the next of kin and patient will be approached, for patients without capacity; just the next of kin will be approached.

Staff: Potential participants will be identified in conjunction with the service manager, then approached by the research team or the Scottish Stroke Research nurses.

5.2 CONSENTING PARTICIPANTS

Co-production: The initial contact will be by a professional already known to the potential participant (e.g. CHSS nurse, stroke consultant in Life after Stroke clinic), to ascertain whether they might be interested. The contact will be made by telephone, to ascertain interest, or by post. To streamline the process, contact by post will include a Patient Information Leaflet and Consent form.

Participants willing to take part will return a consent form to the research team. They will be given as much time as they need to complete and return the form. If we do not hear from them after 2 weeks of sending out the patient information sheet and consent form, we will make contact to check that they have received the invitation pack and consent form.

Research:

Patient and Relatives: A stroke research nurse will obtain consent from the participants -including patients (who are able to give consent) and family members. This applies to both the questions about preferred outcome, the SURE and CollaboRATE questionnaires and the qualitative interviews, and the follow-up telephone calls at 6 months We will give the patient and family up to a week to decide whether to take part, acknowledging that this might mean that they miss the initial assessment at admission.

Family members or carers may be unable to visit the hospital for a number of reasons including the visitation restrictions due to the COVID pandemic. In such circumstances, we shall approach and consent over the telephone ensuring clear documentation of the discussion and persons involved. We will ensure that there will have been contact already made from the clinical care team prior to discussing research. If the family member or carer is willing, the information sheet and consent will be emailed or sent by post (depending on their preference). After having sufficient time to decide, the research nurse will make contact again and sign the consent form on the family members' behalf and send a copy to them.

We do not have the resources to routinely assess whether capacity has returned or not, but if it is clear from discussions with clinical staff and family that capacity has been regained, the patient rather than the next of kin will be invited to complete the questionnaires.

Staff: The stroke research nurse will approach potentially suitable staff who have been identified by the line managers.

5.2.1 Withdrawal of study participants

Participants are free with withdraw from the study at any point or a participant can be withdrawn by the Investigator. If withdrawal occurs, the primary reason for withdrawal will be documented in the participant's case report form, if possible. We will use all data collected up to that point.

5.3 Co-enrolment

All patients who are included in the two audits will be able to be enrolled in other research projects.

If potential participants are already enrolled in other studies, we will recruit them to the co-production workshops and the research elements of the study providing this does not overburden them. If a patient, staff member of family member consents to this study, then co-enrolment to future studies will be allowed, because the current study is not unduly overburdensome.

6. STUDY ASSESSMENTS

6.1 STUDY ASSESSMENTS

Co-production: Five workshops will be conducted via Microsoft TEAMS over a 6 month period, this includes an introductory meeting. Each will last approximately two hours. A summary report will be produced and circulated to all participants at the end of the co-production process.

Research:

Patients and relatives: At recruitment (close to admission) participants (patient with capacity, or next of kin for patients without capacity) will be asked about their preferred outcome (a) if the stroke was so severe that the patient would need nursing home care and (b) as the stroke currently is. The SURE questionnaire and CollaboRATE questionnaires will be applied and free text comments will be invited.

At 2 weeks, 4 weeks and 8 weeks, the SURE and collaboRATE questionnaires will be applied. These time points have been selected as they are the likely time period during which discussions about key decisions are often had (e.g. hyperacute care, fluids, feeding tubes, DNACPR, escalation, antibiotics).

At 6 months after admission, patients who are still alive will be contacted to obtain data on specific abilities (as above) and mRS.

The follow-ups will be conducted either by phone, post or email according to the participants ability and preference.

Those patients or family members invited to take part in qualitative interviews will have these done by telephone or face to face-depending on preference and local

rules around Covid 19 restrictions. If the interviews are performed face-to-face, this will be done in a clinic room in Department of Clinical Neurosciences, or on the ward if the patient is still in hospital. The interviews will be performed just after the 8 week SURE and CollaboRATE questionnaires have been completed and will last approximately one hour.

The table below indicates the study assessments for the research element of this proposal, in which patients with severe stroke and/or family members are recruited as research participants.

Assessment	Baseline/ admission	2 weeks after admission	4 weeks after admission	8 weeks after admission	6 months after admission	Date of discharge/death (may be earlier than previous assessments)
Assessment of Eligibility Criteria	☒					
Written informed consent	☒					
Demographic data, contact details	☒					
Two Questions about preferred outcome	☒					
mRS and specific abilities questions (telephone)	☒				☒	
CollaboRATE and SURE questionnaire	☒	☒	☒	☒		
Extract data from TRAK about actual outcome (death or discharge destination)						☒
Qualitative interview, with a purposively selected sample of patients/family members				☒		

Staff: A focus group with staff members will be conducted in person or via Microsoft TEAMS (depending on COVID restrictions) and will last approximately one hour.

6.2. LONG TERM FOLLOW UP ASSESSMENTS

There will be no long-term follow-up beyond six months after admission, but we will obtain consent from participants to contact them in the future about other research that might be of interest to them.

6.3 STORAGE AND ANALYSIS OF SAMPLES

This is not applicable to this project as we are not collecting samples.

7 DATA COLLECTION

7.1 Source data documentation

Co-production: We will seek written informed consent to audio record (e.g. from Microsoft Teams) the co-production meetings and compile a written and photographic record of the meetings (group activities) and their outputs (prototype materials). Recordings and notes will be stored securely on the NHS Lothian shared drive (password protected with limited access). A summary report will be produced and circulated to all participants at the end of the co-production process.

For stroke survivors this will include name, address, date of birth, gender, type of stroke, time since stroke, occupation. For all other participants this will include name, address, date of birth, gender, occupation.

Audit*:* The additional data fields for this sprint audit will be incorporated into the Scottish Stroke Care Audit. The audit coordinator will extract data on a monthly basis for those with severe stroke (NIHSS of 15 or more on admission) and display on statistical process charts.

Research: The response to the single question about preferred outcome, the four item SURE test and the CollaboRATE questionnaire will be collected on a paper case report form, and then entered into the study database. The study database, designed in REDCap, will be held on the University of Edinburgh intranet. The paper case report form will be stored securely in a locked office along with the consent form.

The qualitative interviews with patients and relative, and the staff focus groups will be recorded, encrypted and also stored securely on NHS Lothian and University of Edinburgh computers. These are password protected with limited access. Transfer of interviews to the transcribers will be via a password protected email system; the transcribers are employed by the University of Edinburgh,

Interviews will be audio recorded on an NHS approved Dictaphone and will be destroyed as soon as results are analysed. Quotations from respondents published will be anonymised and respondents will not be identifiable from the quotes

7.2 Case report forms

Research: Paper case report (CRFs) forms will be used for data collection at baseline; this includes responses to the questionnaire and demographic and clinical variables (stroke type, date of stroke, capacity or not, specific neurological impairments, including aphasia, dysphagia, hemiparesis, any other serious life threatening condition, DNACPR status) and NIHSS score. This data will be transferred from paper CRF to the REDCap database.

The following identifiable data will be stored in the paper case report forms and electronically: name and CHI number, contact details, next of kin (name and contact details). It is necessary to collect this data to allow for follow-ups. This will be stored on an excel spreadsheet, asses registered and will be deleted once the REDCap database has been locked.

Paper CRFs form will be stored by the research team in a locked filing cabinet in a locked office in Professor Mead's office, Royal Infirmary.

To ensure confidentiality of the data collected when published, fictitious site names and pseudonyms or study numbers not linked to sites or persons will be used. All identifiable data such as research site names, address, date of birth and participants' names will be removed.

8. STATISTICS AND DATA ANALYSIS

8.1 SAMPLE SIZE CALCULATION

Formal power calculations and sample size calculations are not needed for this observational study.

Co-production: The sample size is based on our previous co-production work for the NIHR funded RECREATE study to design an intervention to reduce sedentary behaviour after stroke. We aim to recruit 16 participants (equal numbers of lay people and professionals), but will be satisfied if 10 agree. If participants withdraw, or are unable to attend all of the workshops, there will still be sufficient people to develop the intervention.

Audit: We have not performed sample size calculations as we aim to capture data on all severe strokes admitted to RIE. A year of data will enable us to obtain sufficient information to plan the next stage of the study.

Research: We expect at least 200 severe strokes (NIHSS of 15 or above) during months 3-9 of the study. Assuming half are both eligible and consent, we will have data on ~100 patients. This will be sufficient to obtain sufficient precise estimates of proportions (e.g. death/dying/institutional care) and median/interquartile ranges (e.g. for SURE and collaborate questionnaires.

8.2 PROPOSED ANALYSES

Audit data will be displayed on process control charts. These can be extracted from the SSCAS and TRAK on a monthly basis by the Scottish Stroke Care Audit. Simple summary statistics will be used for these data.

Quantitative research data will be analysed using simple summary statistics.

Qualitative interviews will be transcribed using NVivo and analysed using a reflexive thematic analysis (more accessible than grounded theory) which provides flexibility of construction and interpretation.

9. ADVERSE EVENTS

The risk level is low. Although we are addressing a sensitive topic, our previous experience in this area indicates that many families and patients are relieved to be able to talk about a topic that is often on their mind but that health professionals sometimes don't address because of fear of causing distress. If a relative or patient becomes upset with the questions, the discussions will be terminated, the clinical teams informed, and the researcher may make contact with the individual the following day to check that they are OK.

10 OVERSIGHT ARRANGEMENTS

10.1 INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

10.2 RISK ASSESSMENT

Risk assessment, if required, will determine if audit by the ACCORD QA group is required. Should audit be required, details will be captured in an audit plan. Audit of Investigator sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

10.3 STUDY MONITORING AND AUDIT

The ACCORD Sponsor Representative will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

11 GOOD CLINICAL PRACTICE

11.1 ETHICAL CONDUCT.

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

11.2 INVESTIGATOR RESPONSIBILITIES

The investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments.

11. 2.1 Informed Consent

Informed consent applies to the coproduction and research elements of this proposal.

The Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants will receive adequate written information: Participant Information and Informed Consent Forms will be provided. There will also be an oral explanation for the research elements with patients and families. The oral explanation to the participant will be performed by the Investigator or qualified delegated person, and must cover all the elements specified in the Participant Information Sheet and Consent Form. For staff involvement (co-production workshops and focus group with staff), we will provide written information and if additional discussion is needed, further oral information will be provided.

The participant will be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant will given sufficient time to consider the information provided. The participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by regulatory authorities and representatives of the sponsor(s).

The Investigator or delegated member of the trial team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The consent form will be filed in the Investigator Site File (ISF).

The investigator is responsible for ensuring that informed consent is obtained. The process of obtaining this is described above.

If a person decides to withdraw, data collected up until then will be retained

If a patient loses capacity, we will keep data collected up until then and the next of kin will be invited to participate instead. If a family member loses capacity, then the patient will be retained in the study and the data collected from the family member up until that point will be retained.

An informed consent form will be signed by the participant and stored in the Investigator Site file.

11.2.2 Study site staff

The investigators must be familiar with the protocol and study requirements. The Chief Investigator will ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

11.2.3 Data Recording

The Principal Investigator is responsible for the quality of the data recorded.

The study will comply with the 2018 General Data Protection Regulation (GDPR). All identifiable personal data will be kept confidential. Consent forms, paper data collection forms will be kept in a locked filing cabinet, in a locked office in the Royal Infirmary (e.g. Prof Mead's office), as per Good Clinical Practice guidelines. The identifiable data will only be accessed by authorised members of the research team to allow for follow-up.

A Redcap database will be developed and available on the University of Edinburgh computer servers. Digital audio recordings of the coproduction workshops, qualitative interviews and focus groups will be stored on the NHS or University of Edinburgh computers. Researcher process notes, audio recording of co-production group meetings and documents generated by the co-production groups will be transcribed and any identifiable participant information will be removed from the transcripts or process notes. Direct quotations from research participants will be published in research reports and academic journal articles, however, pseudonyms will be used with direct quotations and identifiable information.

Data collected or generated by the study (including personal data) will not be transferred to any external individuals or organisations outside of the Sponsoring organisation.

The University of Edinburgh and NHS Lothian are joint data controllers.

Any data breaches will be reported to the University of Edinburgh and NHS Lothian Data Protection Officers who will onward report to the relevant authority according to the appropriate time lines involved.

11.2.4. Investigator documentation

The Principal Investigator will ensure that the required documentation is available at the local investigator site files (ISF)

11.2.5 GCP training

All researchers are encouraged to undergo GCP training though this is not mandatory. GCP training status for all investigators will be indicated in their respective CVs.

11.2.6 Confidentiality

All forms, reports, and other records will be designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished information, which is confidential or identifiable, and has been disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties

11.2.7 Data protection

All investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation with regards to collection, storage, processing and disclosure of personal information.

Published results will not contain any personal data and be of a form where individuals are not identified and re-identification is not likely to take place.

12 STUDY CONDUCT RESPONSIBILITIES

12.1 PROTOCOL AMENDMENTS

Any change in research activity, except those necessary to remove an apparent, immediate hazard to the participants in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator. Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D approval prior to participants being enrolled into an amended protocol.

12.2 MANAGEMENT OF PROTOCOL NON COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsors and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this will submitted to the REC, and local R&D for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsors every 3 months. Each protocol violation will be reported to the sponsor within 3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. If this study becomes multicentre, deviation logs will be maintained for each site. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

12.3 SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the study

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the co-sponsors (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the co-sponsors to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

12.4 STUDY RECORD RETENTION

All study documentation will be kept for 7 years from the protocol defined end of study point. Study documentation will then be destroyed.

12.5 END OF STUDY

The end of study is defined as the last participant's completion of the final 6 month outcome assessment,

The Investigators or the co-sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, and R+D Office(s) and co-sponsors within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot

A summary report of the study will be provided to the REC within 1 year of the end of the study.

12.6. CONTINUATION OF TREATMENT

The patient's usual clinical care will be continued. The study does not involve provision of any additional treatment.

12.7 INSURANCE AND INDEMNITY

The co-sponsor is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the co-sponsors' responsibilities:

The Protocol has been designed by the Chief Investigator and researchers employed by the University of Edinburgh and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.

The Royal Infirmary, which is part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.

13 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

13.1 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team. Authors of paper will be the researchers listed on the front page of this protocol, and also any other researchers who are employed on the grant, who fulfil the requirements for authorship, as stipulated by the journal to which we submit the paper.

The dissemination strategy will include: a page on the Edinburgh and Lothian Health Foundation website, which will be written in lay terms. All the participants who have consented (i.e. those included in the research element) of the study will be told at the time of consent that they will be able to access the results on this website, and an approximate date when the results will be available.

Results will be disseminated through lay, professional and commissioning forums. Outputs from this study will be published in peer reviewed journals.

14 REFERENCES

[1] Marilyn Kendall, Eileen Cowey, Gillian Mead, Mark Barber, Christine McAlpine, David J. Stott, Kirsty Boyd and Scott A. Murray Outcomes, experiences and palliative care in major stroke: a multicentre, mixed-method, longitudinal study *CMAJ* March 05, 2018 190 (9) E238-E246; DOI: https://doi.org/10.1503/cmaj.170604

[2] Doubal F, Cowey E, Bailey F, Murray SA, Borthwick S, Somerville M, Lerpiniere C, Reid L, Boyd K, Hynd G, Mead GE. The key challenges of discussing end-of-life stroke care with patients and families: a mixed-methods electronic survey of hospital and community healthcare professionals.*J R Coll Physicians Edinb*. 2018 Sep;48(3):217-224. doi: 10.4997/JRCPE.2018.305..

[3] Akila Visvanathan, William Whiteley, Gillian Mead, Julia Lawton, Fergus N Doubal, Martin Dennis. Reporting "specific abilities" after major stroke to better describe prognosis. Journal of Stroke and Cerebrovascular Diseases,
Volume 29, Issue 8, 2020, 104993, ISSN 1052-3057

[4] Visvanathan A, Graham C, Dennis M, et al. Predicting specific abilities after disabling stroke: Development and validation of prognostic models. International Journal of Stroke. January 2021. doi:10.1177/1747493020982873

[5] Visvanathan A, Mead G, Dennis M, Whitely W, Doubal F, Lawton J. Maintaining hope after a disabling stroke: A longitudinal qualitative study of patients' experiences, views, information needs and approaches towards making treatment decisions, Plos One, September 13. 2019 https://doi.org/10.1371/journal.pone.0222500

[4] Visvanathan A, Mead GE, Dennis M, Whiteley WN, Doubal FN, Lawton J.. The considerations, experiences and support needs of family members making treatment decisions for patients admitted with major stroke: a qualitative study. *BMC Med Inform Decis Mak*. 2020 Jun 1;20(1):98. doi: 10.1186/s12911-020-01137-7.

[7] Mason et al Outcome measures to be used in severe stroke Stroke 2021 under review

[8] Flynn, D., Nesbitt, D.J., Ford, G.A. *et al.* Development of a computerised decision aid for thrombolysis in acute stroke care. *BMC Med Inform Decis Mak* 15, 6 (2015). https://doi.org/10.1186/s12911-014-0127-1

[9] Armstrong MJ. Shared decision-making in stroke: an evolving approach to improved patient care. *Stroke Vasc Neurol*. 2017;2(2):84-87. Published 2017 Apr 16. doi:10.1136/svn-2017-000081

[10] Holloway RG, Arnold RM, Creutzfeldt CJ et al on behalf of the American Heart Association Stroke Council, Council on Cardiovascular and Stroke Nursing, and Council on Clinical Cardiology Palliative and End-of-Life Care in Stroke. A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association 27 Mar 2014https://doi.org/10.1161/STR.0000000000000015Stroke. 2014;45:1887–1916

[11] Shafir, A. and Rosenthal, J. (2012) Shared Decision Making: Advancing Patient-Centered Care through State and Federal Implementation. National Academy for State Health Policy.

[12] Straub C, Nebling T, Muller H. Translating research into practice: a German sickness fund supporting patient participation. *Patient Education and Counseling* 2008;73(3):544-50. [DOI: 10.1016/j.pec.2008.07.019]

[13] Alston C, Paget L, Halvorson G, Novelli B, Guest J, McCabe P, et al. Communicating with patients on health care evidence. Washington, DC: Institute of Medicine of the National Academes.2012

[14] Kiesler DJ, Auerbach SM. Optimal matches of patient preferences for information, decision-making and interpersonal behavior: evidence, models and interventions. *Patient Education and Counseling* 2006 Jun;61(3):319-41. [DOI: 10.1016/j.pec.2005.08.002]

[15] Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. *BMJ* 2012;345:e6572. [DOI: 10.1136/bmj.e6572]

[16] Wennberg JE. Practice variation: implications for our health care system. *Managed Care* 2004;13(9 Suppl):3-7. [PUBMED: 15493217]

[17] Coulter A. Engaging patients in their healthcare. How is the UK doing relative to other countries?. Oxford: Picker Institute Europe2006.

[18] Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: What does it mean? (or it takes at least two to tango), Social Science & Medicine, Volume 44, Issue 5,1997, pages 681-692, ISSN 0277-9536, https://doi.org/10.1016/S0277-9536(96)00221-3. (http://www.sciencedirect.com/science/article/pii/S0277953696002213)

[19] Elwyn G, Edwards A, Kinnersley P. Shared decision-making in primary care: the neglected second half of the consultation. Br J Gen Pract. 1999 Jun;49(443):477-82. PMID: 10562751; PMCID: PMC1313449.

[20] Towle A, Godolphin W. Framework for teaching and learning informed shared decision making. BMJ. 1999 Sep 18;319(7212):766-71. doi: 10.1136/bmj.319.7212.766. PMID: 10488010; PMCID: PMC1116602

[21] Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. Patient Educ Couns. 2006 Mar;60(3):301-12. doi: 10.1016/j.pec.2005.06.010. Epub 2005 Jul 26. PMID: 16051459.

[22] Wieringa TH, Rodriguez-Gutierrez R, Spencer-Bonilla G et al Decision aids that facilitate elements of SDM in chronic illnesses: a systematic review Syst Rev. 2019; 8: 121. Published online 2019 May 20. doi: 10.1186/s13643-019-1034-4. PMCID: PMC6528254

[23] Légaré F, Adekpedjou R, Stacey D, Turcotte S, Kryworuchko J, Graham ID, Lyddiatt A, Politi MC, Thomson R, Elwyn G, Donner-Banzhoff N. Interventions for

increasing the use of SDM by healthcare professionals. Cochrane Database of Systematic Reviews 2018, Issue 7. Art. No.: CD006732. DOI: 10.1002/14651858.CD006732.pub4

[24] Elwyn G, Stiel M, Durand MA, Boivin J. The design of patient decision support interventions: addressing the theory-practice gap. *J Eval Clin Pract*. 2011;17(4):565-574. doi:10.1111/j.1365-2753.2010.01517.x

[25] Street RL, Makoul G, Arora NK. Epstein RM. How does communication heal? Pathways linking clinician–patient communication to health outcomes,Patient Education and Counseling, Volume 74, Issue 3,2009, Pages 295-301,ISSN 0738-3991,https://doi.org/10.1016/j.pec.2008.11.015.(http://www.sciencedirect.com/science/article/pii/S0738399108006319)

[26] Shay LA, Lafata JE. Where is the evidence? A systematic review of shared decision making and patient outcomes. Med Decis Making. 2015 Jan;35(1):114-31. doi: 10.1177/0272989X14551638. Epub 2014 Oct 28. PMID: 25351843; PMCID: PMC4270851.

[27] Forster A, Brown L, Smith J, House A, Knapp P, Wright JJ, Young J. Information provision for stroke patients and their caregivers. Cochrane Database of Systematic Reviews 2012, Issue 11. Art. No.: CD001919. DOI: 10.1002/14651858.CD001919.pub3

[28] Bruno A, Akinwuntan AE, Lin C et al Simplified Modified Rankin Scale Questionnaire. Reproducibility Over the Telephone and Validation With Quality of Life. Stroke 2011;42:2276–2279

[29] Légaré, F., 2010 et al. Are you SURE? Assessing patient decisional conflict with a 4-item screening test, [online] available at http://www.cfp. ca/content/56/8/e308.full (and described in NHS England 2012. Measuring shared decision making ; https://www.england.nhs.uk/wp-content/uploads/2013/08/7sdm-report.pdf)

[30] Barr PJ, Thompson R, Walsh T, Grande SW, Ozanne EM, Elwyn G The Psychometric Properties of CollaboRATE: A Fast and Frugal Patient-Reported Measure of the Shared Decision-Making Process J Med Internet Res 2014;16(1):e2. URL: https://www.jmir.org/2014/1/e2 DOI: 10.2196/jmir.3085. PMID: 24389354. PMCID: 3906697

[31] Braun V, Clarke V, Hayfield N, Terry G. 2019. Thematic Analysis. In: Handbook Res Methods Heal Soc Sci [Internet]. Singapore: Springer Singapore; [cited 2019 Nov 4]; p. 843–860. Available from: http://link.springer.com/10.1007/978-981-10-5251-4_103

[32] Braun V, Clarke V. 2006. Using thematic analysis in psychology. Qual Res Psychol [Internet]. [cited 2019 May 20]; 3:77–101. Available from: https://www.tandfonline.com/action/journalInformation?journalCode=uqrp20

[33] Hoffmann TC, Glasziou Paul, Boutron I, et al Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide *BMJ* 2014; 348 :g1687. TIDIER reference https://www.equator-network.org/wp-content/uploads/2014/03/TIDieR-Checklist-PDF.pdf