Pre-hospital specialist triage of potential stroke patients using digital technology: a rapid service evaluation to capture learning and impact of innovations prompted by the COVID19 pandemic

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Key points about this evaluation

What are we evaluating? Digital systems that allow stroke specialists to remotely assess potential stroke patients while patients are being attended by ambulance services.

Why is this important? By allowing stroke specialists to assess potential stroke patients sooner using digital communication tools, systems of this kind may help ensure a) stroke patients are transferred to a specialist stroke unit and b) non-stroke patients are transferred to a more appropriate service (or remain in their home/care setting). However, little is known about how such systems work, or their impact on quality of care, outcomes, or patient safety.

Where is this taking place? North Central London and East Kent.

Which questions will we address?

1. Are the digital remote assessment systems acceptable to their users (stroke clinicians and paramedics)?
2. Are the systems effective in terms of usability and image/sound quality?
3. Do the systems support appropriate, safe transfer of potential stroke patients?
4. Which factors influence uptake, implementation and impact of these systems?
5. Which aspects of these systems should be retained post COVID-19 and which adaptations (if any) are required to support their implementation?

Which approaches will we use?

1. Rapid scoping review of relevant literature
    a. Describe relevant concepts and current knowledge, identify gaps, and suggest how service evaluation might help address these
2. Quantitative analysis of local data and national audit data:
    a. Frequency of use, ease of use, technical stability, image/sound quality
    b. Safety, including timeliness and appropriateness of patient transfer
    c. Delivery of key clinical interventions
3. Qualitative analysis of interviews, meeting observations, and documents:
    a. Implementation and governance of new systems
    b. Perceptions of acceptability, usability, and safety

How might this evaluation support the NHS?

1. Support local emergency response systems and stroke services in assessing the effectiveness and safety of digital remote assessment systems
2. Support implementation of similar systems elsewhere in the English NHS
3. Support national efforts to improve the pre-hospital pathway for stroke patients through the Long Term Plan.

Overview

The NIHR Rapid Service Evaluation Team (NIHR RSET) has been funded by the NIHR Health Services and Delivery Research Programme to conduct rapid evaluations of new ways of providing and organising care. Clinical leaders in North Central London and East Kent have asked NIHR RSET to evaluate new digital systems which allow stroke specialists to examine and prioritise ('triage') potential stroke patients before they reach hospital. These new systems are being piloted by stroke specialists and ambulance services in response to the COVID-19 pandemic.

Working with local stroke and ambulance services, NIHR RSET will conduct a rapid mixed method service evaluation. The evaluation will include a rapid scoping review of available evidence on remote pre-hospital triage for potential stroke patients using digital technologies, with a particular focus on implementation factors and how technology may assist real-time clinical decision making. It will also include analyses remote triage systems that are being piloted in two areas: NC London and East Kent. We will use qualitative data (documents, interviews, and meeting observations) and quantitative data (locally-collected measures and national audit data) to analyse the perceived usability, acceptability, and safety of the new triage systems, and their impact on care delivery.

The lessons generated through this evaluation will be of use to service planners and stroke and ambulance services. Locally, lessons will inform decisions about potential further implementation of remote triage systems for stroke across London and the South East Coast. Nationally, they may influence the prehospital workstream for delivery of the NHS Long Term Plan. Finally, this work will potentially lead to development of a larger research proposal.

Background

Optimising access to organised stroke care in the English NHS

Stroke is a major cause of death and disability, in the UK and internationally.[1] Evidence from urban settings suggests that centralising stroke systems into a small number of hyper acute stroke units (HASUs, which offer rapid access to stroke specialist assessment and treatment, including clot-busting therapies if appropriate) is linked with better care delivery and outcomes.[2-5] Such systems rely on effective collaboration between multiple stakeholders, including hospital stroke services and ambulance services, to ensure appropriate transfer of patients to HASU.[6-8]

The NHS Long Term Plan reinforces the role of networked stroke systems at regional level to improve care delivery and clinical outcomes.[9] Integrated Stroke Delivery Networks (ISDNs) are made up of multiple health agencies, including ambulance Trusts, and aim to ensure that NHS stroke services comply with seven-day quality standards for stroke care and National Clinical Guidelines for Stroke. In addition, there is support at the highest level of the NHS to scale up technologies that improve the quality of stroke services, such as through the potential use of artificial intelligence to interpret CT and MRI scans and the implementation of telehealth.

Minimising unnecessary transfer to specialist stroke units using telemedicine – progress in England

Digital technologies have potential to support more effective stroke care systems, such as at the pre-hospitalisation triage stage, through the utilisation of mobile devices or telemedicine that connects clinicians to patients remotely. For example, because of limited specificity of screening tools for stroke (e.g. FAST), acute stroke services commonly manage large numbers of potential stroke patients who turn out to have different conditions (so-called

'mimics').[10] Specialist stroke assessment via telemedicine has been found to support accurate triage of patients[11] and has potential to identify patients who do not need urgent treatment in a specialist unit. However, to date, the piloting and implementation of such technologies has been limited in England. Reported obstacles to adoption include technical issues (e.g. reliable video-signals), and cultural barriers (e.g. anecdotally, paramedics' unwillingness to reach out for advice of this kind from stroke consultants).

International evidence for "telestroke" and mobile stroke units

Elsewhere, there has been movement towards the uptake of telemedicine in stroke care, particularly in the US and Germany, with emerging evidence about its safety and cost-effectiveness.[12,13] For example, an editorial by Demaerschalk and Levine presents studies to support the argument that the uptake of telemedicine in stroke care can effectively provide neurologic expertise in real-time, within the tight time window necessary for urgent stroke treatment. They cite evidence that telemedicine (termed "telestroke") is superior to telephone-only options and "can rival outcomes from an in-person stroke team treatment".[11]

There may, however, be issues with the usability of new telestroke systems or mobile facilities that rely on visual cues from clinicians' perspectives. Chapman Smith et al. (2019) evaluated the implementation of pre-hospital stroke intervention - an ambulance equipped with a mobile telemedicine system to perform remote stroke assessments. The researchers gathered data through surveys and formative feedback about the usability of the technology (e.g. audibility) and recommend that mobile systems should make use of 'clinical simulation' and a Plan-Do-Study-Act (PDSA) approach to optimise implementation.[14]

French et al. (2013) provide a systematic review of the challenges of implementing a telestroke network having identified 61 telestroke projects and international evidence about barriers and enablers for adoption. The major barriers reported include: 'reluctance because of unfamiliarity' and 'conflict with cultural norms'; technical issues with audio-visual quality (although rare); lack of staff confidence in systems; lack of IT support; poor communication between centres and disciplines.[15] The authors also note that in addition to clinical outcome process measures, evaluators should attend to the impact of new systems on decision making (e.g. via a 'decision support log') and the acceptability of the technology (e.g. through staff and patient satisfaction questionnaires).

A recent scoping review indicates that there is a small but growing evidence base on how remote technologies may support ambulance staff in triaging potential stroke patients, including use of pre-hospital biomarkers and imaging, and mobile telemedicine.[16] The review reports no UK-based research on ambulance telemedicine systems to support remote assessment by stroke clinicians. However, the international research reported indicates that such systems are viewed positively by staff and can result in reduced time to care interventions, and that pre-hospital remote diagnosis can be as accurate as hospital-based diagnosis.[16] The review also noted relatively little data to suggest such systems result in more effective redirection of patients, or about their impact on outcomes such as patient safety.[16]

Understanding the implementation of digital innovations in healthcare systems

There is an increasing interest in how innovative digital technologies come to be adopted and used in healthcare systems and may shape clinical practices and workflows. For example, recent WHO guidance suggests digital health should be understood in terms of an ongoing process of development, where digital interventions evolve from early piloting and prototyping to digital maturity, requiring 'real time' monitoring of both technical functionality and stability in addition to health outcomes.[17] A recent analysis of health service innovation describes the key factors influencing implementation of innovative ways of working, which

are summarised in Figure 1.[18] These factors include the nature of the innovation, ways in which it is implemented, the settings into which it is introduced, and the wider context for change, reflecting broader literature on diffusion of innovations.[19]

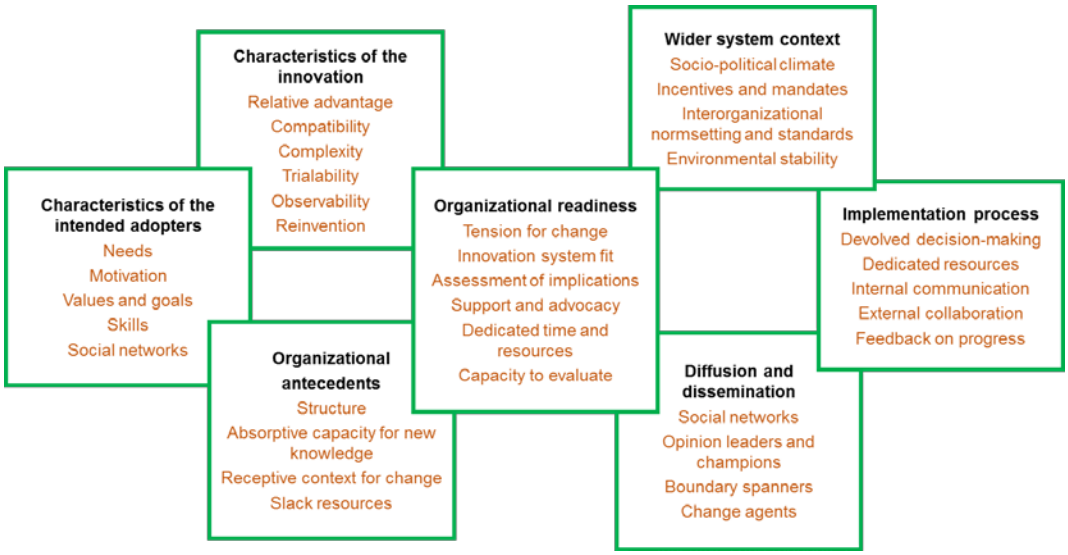

Figure 1. Key factors influencing adoption and sustainability of innovations in healthcare (adapted from Nolte, 2018)[18]

NHS service context

North Central London is served by a single Hyper Acute Stroke Unit (HASU), hosted by UCLH NHS Foundation Trust. Under normal circumstances, the UCLH HASU mainly works with four stroke units (SUs). This is part of the wider London 'hub and spoke' model implemented in 2010, where all suspected stroke patients were eligible for initial treatment in a HASU (hub) and ongoing acute care in an SU (spoke) near home.[7]

East Kent is part of a region that has been working to centralise its stroke services into a reduced number of HASUs over several years. Under normal circumstances it is served by two HASUs, at William Harvey Hospital and Queen Elizabeth the Queen Mother Hospital.

Responses to COVID-19

These regional stroke systems report having responded to COVID19 in a number of ways:

1. **Introduction of digital pre-hospital triage systems**
   North Central London and East Kent have introduced 'on-scene' digitally-supported systems to allow paramedics to have remote contact with senior stroke clinicians to help establish whether a patient is suitable for transfer to HASU or an alternative care pathway. This is in line with wider acknowledgement at national level that digital systems of this kind may be of value in sustaining specialist care pathways and minimising unnecessary transfer to hospital during the current crisis.[20]
2. **Relocation of specialist services**
   East Kent has moved rapidly to a more centralised system, with all HASU provision moved to Kent and Canterbury Hospital. The UCLH HASU has been moved to Queen's Square (co-located with the UCLH Stroke Unit and neurology services).
3. **Fewer patients reaching HASU**
   It is reported that fewer patients are being treated in HASUs at present; this has implications for quality of care and patient outcomes. While this may be due to

ambulance services transferring patients to local hospitals, other explanations might relate to fewer strokes being reported in the community.

4. **Repurposing of stroke resources**
   London Stroke Unit (SU) beds are being repurposed and staff redeployed to care for COVID-19 patients.

The innovation: digital pre-hospital triage

Both North Central London and East Kent are introducing 'on-scene' digitally-supported systems that let paramedics contact acute stroke services for remote clinical assessment using digital communication platforms (such as Facetime), via communications devices (such as smartphones, computers, and iPads). The aim is to establish whether a patient is suitable for transfer to a HASU or should be on a different care pathway, thus minimising unnecessary transfers or delays. Decisions are to be informed by system feedback about hospital's capacity, including HASUs. The anticipated benefits of this system will be to:

A) Ensure the continuation of appropriate referrals during the COVID-19 pandemic – e.g. continued transfer to HASUs or another pathway if appropriate (e.g. alternative provider / remote service)
B) Ensure the timeliness of treatment for optimal patient outcomes, in accordance with best practice guidelines
C) Help services to run as smoothly and efficiently as possible – e.g. by providing decision support to paramedics on the ground.

There are some contrasts in how the interventions in NC London and East Kent have been implemented:

- *Who assesses*: in East Kent, stroke consultants will provide assessments during the day, while neurology trainees will provide assessments out-of-hours; in NC London, stroke consultants will provide assessments 24/7.
- *Who is assessed*: in East Kent, patients where there is uncertainty about stroke diagnosis are eligible for remote triage; in NC London, all potential stroke patients are eligible to go through remote triage.
- *Timing of implementation*: in East Kent, the pilot commenced for potential stroke patients in the week beginning 6th April 2020; in NC London, the pilot commenced on 17th May in the northern sector of this area, with the aim to roll-out across NC London when possible; London-wide roll-out is anticipated in autumn 2020, pending evidence of the safety and effectiveness of the pilot.

It is important to establish the acceptability and safety of this intervention, as perceived by stroke and ambulance staff. There is also potential to support identification of issues (technical and otherwise) and with key stakeholders (e.g. stroke clinicians, paramedics, operational planners, and service managers) both during the pilot implementation process and retrospectively.

Rapid service evaluation

Aim

We will conduct a rapid, mixed methods service evaluation[21,22] of how pre-hospital triage to support appropriate HASU attendance is facilitated by new service models using digital technologies that enable remote clinical input.

Service evaluation questions (agreed with stakeholders)

1. Are the pilot remote assessment systems acceptable to their users (stroke clinicians and paramedics)?
2. Are the systems effective in terms of usability and image/sound quality?
3. Do the systems support appropriate, safe transfer of potential stroke patients?
4. Which factors influence uptake and impact of these systems?
5. Which aspects of these systems should be retained post COVID-19 and which adaptations (if any) are required to support their implementation?

Design

This will be a rapid mixed methods service evaluation. It will incorporate a review of the published evidence, including available systematic reviews (e.g. on telestroke, telemedicine and mobile pre-hospital interventions used in emergency stroke care) and analysis of pilots implemented in NC London and East Kent to aid understanding of real-world implementation.

Detail on the proposed methods and approached can be found below and in **Table 1**. Our approach will reflect recent recommendations for rapid service evaluation[22,23] and concepts related to implementation and evaluation of digital and other health interventions.[17,18] Such approaches aim to maximise the successful implementation of a new technology, both over the course of piloting and wider implementation in the longer term, by ensuring it is adaptable to staff behaviours and organisational needs.

Rapid scoping review of the literature

We will undertake a rapid scoping review[24,25] of literature on digital and telemedicine/telestroke interventions used to triage potential stroke patients at the pre-hospital stage. The review will be conducted in two phases, and its objectives will be to:

- Define relevant concepts, key terms and summarise what is currently known about digital interventions used in the triage of potential stroke patients (through a rapid appraisal of existing reviews and primary studies)
- Identify any conceptual frameworks or theories used to understand the implementation of digital interventions in this context
- Identify any gaps in research or evaluation knowledge
- Determine how our evaluation and future research might address these gaps

Phase 1: Review of existing reviews

Our first step will be to quickly identify any existing systematic, scoping, or rapid reviews on this topic using key words (e.g. telemedicine, telestroke, stroke, ambulance/paramedic, triage and review) published in the last five years. The search will be limited to peer-reviewed outputs published in English. A member of the team will lead this search using a range of databases and resources (e.g. Cochrane Library, ACM Digital Library, Web of Science, Epistomonikos and PROSPERO). The findings from this phase will be summarised in a short umbrella 'review of reviews' paper that will inform the design of the detailed rapid scoping review in Phase 2, thus helping to avoid any unnecessary duplication with existing reviews. The findings will also be used to inform the design of interview topic guides to be used in the qualitative work.

Phase 2: Rapid scoping review

The design of the final rapid scoping review will be determined by the results of Phase 1 and will be guided by recommendations on conducting scoping reviews.[24,25] We will adopt an approach suitable for identifying conceptual frameworks and social science perspectives that

shed light on the implementation of technology in health care settings (e.g. usability, enhanced communication, safety) and may impact on quality and outcomes of care. We will also identify any knowledge and evaluation gaps, such as whether any economic impact analyses have been conducted about similar service innovations within pre-hospital stroke triage. Any such review will be reported following PRISMA-ScR recommendations and summarised as a concise report featuring headline findings to share with our collaborators. Eligible primary research studies will be critically appraised for quality by several members of the team.

Analysis of pilot implementation

We will analyse implementation of the prehospital triage pilots in NC London and East Kent, synthesising a range of quantitative and qualitative data (see **Table 1**), with findings organised around themes emerging from the scoping review.

Quantitative analyses – insights on usability, safety, and delivery of key interventions:

We will analyse the pilot triage systems in terms of user perceptions, delivery of the pilot triage systems, and delivery of key clinical interventions.

Usability: we will analyse data collected through short feedback surveys, which are to be collected by local services shortly after the remote triage process.

- We will analyse users' views of the systems' usability, technical stability, image/sound quality, and influence on patient destination.
- We will analyse descriptively whether and in which ways user perceptions change over the course of the pilot phase, e.g. the influence of increased experience, or of the system 'bedding in'.

Safety: we will analyse novel datasets that are being designed and collected by the participating stroke and ambulance services. Using these data we will analyse:

- Timeliness of patient transfer, including remote triage call duration, ambulance call-out duration, ambulance journey time (to HASU or other services)
- Appropriateness of patient transfer (e.g. influence of remote triage on patient destination, and whether a decision not to transfer to HASU was revised following arrival at a non-HASU site).
- These data will be analysed descriptively, in order to assess how timeliness and appropriateness of patient transfer are influenced by e.g. case complexity and seniority of stroke clinician conducting the remote assessment. Non-parametric analyses of association between these factors will be considered.

Delivery of key clinical interventions: we will analyse national audit data (via the Sentinel Stroke National Audit Programme [SSNAP]) in the participating regions. We will analyse:

- Numbers of stroke patients treated by stroke teams
- Proportion of stroke patients receiving key clinical interventions (e.g. time to brain scan, swallow assessment, and thrombolysis where appropriate).
- These data will be analysed descriptively, at team (i.e. local stroke teams) and regional (i.e. NC London and East Kent) levels. We will examine these data against past performance at team level in order to identify any changes in care delivery during the pilot phase.

Data requests

We will request local data via participating NHS organisations. We will request SSNAP audit data via HQIP. Collaborators Hargroves and Simister confirmed that their localities have continued to submit SSNAP data. The SSNAP team have also confirmed that a request for

team-level data will be seen as low risk and processed rapidly. We are engaging regularly with clinical collaborators and the SSNAP team for updates on audit participation and data quality.

Qualitative analyses – insights on usability, acceptability, and safety:

Qualitative methods – interviews, non-participant observations of meetings, and documentary analysis - will be used to analyse implementation of the pilot digital triage systems, including users' perspectives on usability, acceptability, cognitive load, and patient safety (e.g. potential delays in care, appropriateness of patient transfer). We aim to:

- Provide rapid evidence about the perceived impact and effectiveness of the triage systems being piloted – e.g. any immediate issues with implementation (including technical issues that have been addressed and modified, or could be in future) and users' early and later impressions.
- Capture learning about the service innovation and staff experiences of the remote assessment process

First, we will conduct remote interviews or if more convenient group discussions (using e.g. telephone or video calls) with a particular focus on hospital and ambulance staff who have been using the pilot systems. In Phase 1, in each region we will interview up to 15 paramedics and up to 5 stroke team staff (including clinicians, managers, and associated staff supporting pilot implementation). Interviews will explore views of the new digitally-enabled pre-hospital triage systems, in terms of acceptability, usability (e.g. reported cognitive load), and perceived implications for patient safety. Depending on uptake of the triage system, we will potentially conduct follow-up interviews (numbers to be confirmed) to assess long-term use and any changes in perceptions of the tools and digital triage system as a whole. We thus aim to capture changes in staff perceptions as they gain familiarity with the new systems.

Second, we will conduct non-participant observations of relevant stakeholder or operational meetings that the evaluation team are invited to (such as those held bi-monthly by NCL, which we have been invited to attend). The focus of the observations will be 1) to understand developments as the pilots progress and are potentially scaled up, and 2) to analyse oversight, governance, and management of the pilots, for example in responding to technical or safety issues.

Third, we will conduct documentary analysis (of e.g. educational, guidance or technical materials such as triage flow diagrams) to provide ongoing insights about the triage systems as they develop.

Recruitment and sampling

Participation in this service evaluation will only happen with fully informed consent. For interviews, potential participants will be sent an information sheet. They will have at least 48 hours to consider the contents of information sheets and will be free to ask any questions about the project. Interviews will be conducted and recorded only after participants have provided informed consent. Interviewees will be free to withdraw at any time, up to and during the actual interview or focus group. Participant details will be anonymised in the data, and participants will not be identified by name/organisation in any outputs (e.g. reports or publications) of the project.

We aim to sample respondents in order to gain perceptions of those with first-hand knowledge of using the system. We propose to sample a mix of paramedics and hospital-based stroke perceptions involved in the pilots, including a range of those who have reported initial technical issues with the systems and those that have not.

For observations, meeting members will be sent an information sheet in advance, alongside other meeting papers. We will ask the Chair to announce the evaluation team's presence at the beginning of the meeting and confirm that no names will be used in the final report. If sensitive issues come up which those present at the meeting would rather were not observed, at this point, the evaluation team can 'dial out' of the meeting and return when the Chair communicates that it is appropriate to do so.

We do not propose conducting any in-person interviews or observations due to the Covid-19 situation unless national, NHS and university safety advice changes during the evaluation, and meetings move to a different format. We will keep monitoring the national situation and current guidance.

Data capture and analysis

Emerging data (including interviews, observations, and documents) will be captured using Rapid assessment procedures (RAP) sheets.[23] These sheets ensure the iterative nature of the evaluation by facilitating data collection and analysis in parallel. An initial version of the RAP sheet is developed in relation to interview and observation guides, but the sheet is refined throughout the evaluation in relation to the data. Each member of the evaluation team involved in data collection will manage their own RAP sheet and one team member will act as a 'cross-checker' of the data to ensure consistency in data collection and analysis. The RAP sheets will be updated after each instance of data collection (e.g. interview, meeting observation), facilitate quick and ongoing analysis and feedback with stakeholders.[26]

Transcripts from the interview recordings will be imported into NVivo and analysed using framework analysis. The categories used in the framework will be guided by our evaluation questions and the main findings included in the RAP sheets, but we will also be sensitive to topics emerging from the data.

Synthesis of findings

We will draw together findings from the quantitative and qualitative analyses in the following ways, in order to provide insights on the pilot triage systems in terms of design, implementation, usability, and safety. For each pilot area, we will draw on qualitative interviews to identify factors that might help explain patterns observed in the quantitative data. We will also analyse across the two areas, for example in order to identify common lessons for implementation, which we will in turn use to further reflect on our local pilot areas. Finally, these findings will be organised around themes emerging from the rapid scoping review, in order to identify where they sit in the existing literature.

Formative feedback and learning together

The evaluation team will provide formative feedback about the digital pre-hospital triage systems being adopted to a virtual stakeholder group over the course of the evaluation. We will convene this group to include clinical leads from participating stroke and ambulance services and operational planners in both pilot areas. This group will meet at a frequency agreed with localities to reflect on the emerging results, share learning from the different sites, and identify and drive any actions or data capture that might be required (either locally or across all sites). Interim updates on progress and findings will be shared with stakeholders on a weekly basis (in line with our collaborators' preferences). We will also seek to deliver meaningful findings to facilitate local decision-making, for example providing findings to support local discussions of further implementation of the remote triage systems.

Dissemination: sharing summative feedback and lessons

The evaluation will generate findings to inform the future implementation of digitally-enabled, remote services in stroke care in England, with reference to the aims of the NHS Long Term Plan. Lessons will be identified from, a) a rapid scoping review; b) a rapid, empirical evaluation using mixed methods. The inclusion of two pilot areas will help to identify any important contextual characteristics or regional issues that influenced the implementation of digital technologies and changes to practice during COVID-19.

At the end of the evaluation, the virtual stakeholder group will be asked to meet again, with an extension of the invitation to a wider network of stroke and ambulance staff, to share learning, reflect on findings – particularly in relation to previous research and pilots[27] – and agree next steps to disseminate the learnings and insights nationally. Such an event (either in person or held as an online webinar and Q&A session) could also serve as a way to acknowledge the efforts of staff in delivering service innovations through this crisis.

We will seek to publish key findings in academic journals. Alongside this, in consultation with stakeholders, we will produce resources summarising the learning from this evaluation. This will include an accessible, learning-focused report, supplemented with a bundle of slide decks targeted at different audiences (e.g. clinical and system leads, policy makers, and patients and the wider public. We will engage with our networks, including NHSE/I (e.g. the Getting It Right First Time programme and the NHS Long Term Plan team), and the Stroke Association, to maximise the uptake of learning from this analysis.

Patient and public involvement (PPI)

Two patient representatives have provided feedback on the protocol design and will provide ongoing review and feedback throughout the evaluation (including dissemination).

We are working with local collaborators to ensure we have an effective local involvement and engagement strategy. We will contact local patient groups or individuals to involve them in the evaluation.

Ethical issues

We have self-assessed our protocol using the Health Research Authority's 'Is my study research?' tool: the tool suggests that our project would not be considered research by the NHS. We will next share the evaluation protocol and materials with our local R&D Office and UCL Ethics Committee to confirm that the project can be classified as a service evaluation, thus not requiring approval by a research ethics committee. As stated above, we are aware of the sensitive nature of this evaluation for organisations and individuals. The team has experience in conducting evaluations and research on similarly sensitive topics, and it will be conducted to highest ethical standards.

Information sheets will be provided to potential interviewees with information on the evaluation (purpose, design, expectations, risks, and benefits) before they are asked if they would like to take part in an interview. The information sheet will indicate that the evaluation team act independently, operate under a professional code of conduct, and are interested in all aspects of the SMQ and challenged providers regimes (both positive and negative). We will maintain the anonymity of the participating organisations and individuals.

Project management

As Project Lead, Angus Ramsay (NIHR RSET, UCL) will be responsible for delivery of the evaluation, including obtaining relevant governance permissions, and ensuring the evaluation is delivered according to the protocol; he will lead the quantitative analysis (including data requests), support the qualitative data analysis, and support the write-up of

the rapid scoping review. Jean Ledger (NIHR RSET, UCL) will lead the rapid scoping review and lead the qualitative data collection and analysis. Cecilia Vindrola (NIHR RSET, UCL) will provide expert advice on the qualitative data analysis and scoping review, including expertise on rapid evaluation methods. Sonila Tomini (NIHR RSET, UCL) will provide expert advice on the quantitative analyses. Professor Naomi Fulop (NIHR RSET and UCL) will provide project oversight.

The team will work closely with clinical collaborators throughout the evaluation, to ensure optimal approaches to data collection, analysis, interpretation, and sharing of lessons. Clinical collaborators are David Hargroves (East Kent Hospitals University Trust and National Clinical Lead for Stroke GIRFT Programme), Rob Simister (University College London Hospitals NHS Foundation Trust and Joint Clinical Director for London Stroke System), and Patrick Hunter (London Ambulance Service). South East Coast Ambulance NHS Trust have confirmed support for the proposal; over the course of protocol development we will identify a named collaborator from this organisation.

The team will meet weekly during the early phases of the project and at least monthly thereafter throughout the duration of the project. The evaluation will be discussed as a standing item at monthly NIHR RSET meetings, in terms of progress against project milestones and to address any practical or methodological issues, and to help maintain the independence of the evaluation.

All team members - NIHR RSET and clinical collaborators – will contribute to interpretation, write-up, and sharing of findings.

Insurance

University College London holds insurance against claims from participants for harm caused by their participation in this evaluation. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this evaluation is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the evaluation. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is a NHS Trust or otherwise.

Data management

Data Transfer

In the evaluation, interview data will be collected from participants in accordance with the participant information sheets and the section on recruitment in this protocol. Interviews will be recorded on an encrypted, password-protected digital audio recorder to which only the evaluation team member knows the password. The data will be anonymised and stored securely on a shared drive within the UCL password-protected IT network, which can only be accessed by named members of the qualitative team. The data will be cleared from the digital audio recording device when it has been transferred. These data will be kept completely separate from other evaluation data. Anonymised interview data will be organised by participant codes. Participant identifier codes will be stored in a password-protected file on a secure drive to which only named team members have access via the UCL password-protected IT network. Participant identifier codes will be stored separately from the anonymised interview transcripts.

The digital audio recordings of interviews will be appropriately sent to Essential Secretary via secure FTP system (http://www.essentialsecretary.co.uk/) for transcription. Digital audio recordings of interviews, the anonymised interview transcripts, data for the documentary

analysis, and quantitative data will be stored for analysis on a secure drive to which only named team members have access via the UCL password-protected IT network.

All electronic data will be held on the UCL file servers, in shared or in personal folders. Access to data is granted after login with valid accounts and according to access permissions. The accounts are created centrally only for personnel registered at UCL. The data can only be accessed through the Department of Applied Health Research secure server and only by identified UCL evaluation team members.

Data Archiving

The participating site recognises that there is an obligation to archive evaluation -related documents at the end of the evaluation (as such end is defined within this protocol).The evaluation team will store personal identifiable data up to one year after the evaluation has ended. Participants will be informed of this storing requirement through the participant information sheet. The Chief Investigators confirm that they will archive the evaluation master file at UCL for 10 years from the evaluation end.

Risk and risk management

The timeline proposed below is based on the following assumptions: 1) the pre-hospital triage systems have sufficient uptake (discussions with clinical collaborators indicate this to be the case); 2) the team have timely access to the data required for the qualitative and quantitative analyses.

Funding

NIHR RSET is funded by the NIHR Health Services and Delivery Research (HS&DR) programme (HSDR 16/138/17).

Quality control

The evaluation protocol has been reviewed by independent experts in evaluating digital innovations in healthcare settings and organisation and delivery of emergency and pre-hospital care and two patient representatives. It will also be reviewed by representatives from the UCL/UCLH Joint Research Office and National Institute for Health Research (NIHR). Once approved by the NIHR, the final protocol will be submitted for publication. Quality control of other outputs – e.g. academic papers and project summaries – will be shared with the wider NIHR RSET programme over the course of their development to ensure analytical rigour and maintain independence of the work.

Project timeline (June 2020-March 2021)

- **June-17th July**: protocol development, peer review, and NIHR sign-off
- **June-July**: search for existing evidence reviews (phase 1)
- **24th July**: confirm service evaluation status with HRA and UCL
- **24th July**: East Kent and NC London HASU data requests
- **24th July**: SSNAP data request
- **July-November**: rapid scoping review (phase 2)
- **August-January 2021**: qualitative and quantitative data collection; rolling analysis
- **Mid-September**: interim report 1 (scoping review; initial qualitative/quantitative findings)
- **January 2021**: interim report 2 (advanced findings, informed by stakeholders)
- **March 2021**: final report: lessons and recommendations from both pilots, organised around the scoping review findings, and outputs designed for different audiences (e.g. clinical and system leads, policy makers, and patients and the wider public).

Table 1. Summary of evaluation methods as part of a rapid evaluation cycle

Analysis	Approach/measure	Rationale	Data/resources required	Lead/s
Rapid scoping review of the literature	Phase 1: review of reviews Phase 2: rapid scoping review (focus/approach to be determined by Phase 1)	Identify methods used to evidence telestroke interventions and lessons from implementation internationally	Two NIHR RSET members conduct search, a third reviews abstracts and help write rapid summary document. Expert clinical input if required via collaborators.	JL, supported by CV, AIGR, & NJF
Quantitative analyses	Post-completion tool - 3 items: A. ease of use [Likert scale 1-5]; B. Technical issues (signal stability, image/sound quality) C. Influence on patient destination [Y/N]	Assess perceptions of usability	Questions asked by stroke physician at end of remote triage consultation	AIGR, supported by ST
	Number of calls; Diagnosis; Recommended patient destination; call duration; journey duration Mapping where patients are being treated for stroke across regions; Appropriateness of transfer (e.g. avoiding unnecessary transfer for non-stroke patient or need for transfer to HASU if redirected to non-HASU site)	Assess safety and delivery of system Assess influential factors, e.g. of case complexity and who provides feedback (stroke physician Vs neurology trainee)	Via local HASU and ambulance services	
	Delivery of key clinical interventions	Assess delivery of care at stroke team and regional levels	SSNAP Data (team level)	
Qualitative analyses	Telephone interviews (***per pilot area***) Phase 1: • Paramedics: up to 15 • Stroke staff*: up to 5 • Total: up to 20 Phase 2: pending data on uptake *includes physicians, managers, and other operational staff	Gather perceptions of digital triage system, in terms of acceptability, usability and patient safety. E.g., did system increase time to hospital, or did expert advice improve decision?	Interviews up to 15 minutes each Rapid follow-up of staff (within a week of experiencing triage system).	JL, supported by AIGR, CV, & NJF
	Remote observations of meetings	Understand governance of pilots, e.g. managing safety issues, oversight of implementation and roll-out.	Remote access to meetings	

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