Stroke

Phase 3 Funding Competition

SBRI HEALTHCARE

Health Innovation Network

Proudly working with Stroke Association

Accelerated Access Collaborative

NHS

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Executive Summary

Evidence-based and cost-effective interventions can fail to be implemented into routine health and social care practices, a challenge which could be addressed by real-world validation of innovations in their intended setting and by accelerating their uptake and facilitate adoption and spread.

The SBRI (Small Business Research Initiative) Healthcare Programme is committed to supporting the NHS in delivering the objectives of the NHS Long Term Plan (LTP). Phase 3 funding supports implementation studies that generate the evidence in real-world settings necessary to progress towards future uptake and provide potential adopting organisations with an understanding of the implementation pathway and assurance of benefit delivery.

In 2024/25, SBRI Healthcare Phase 3 seeks to address challenges in **Stroke** and aims to identify solutions at an advanced stage of development which help tackling:

1. Early diagnosis
2. Rehabilitation
3. Life after stroke.

Applicants are asked to consider the impact of their innovation on the whole system and to be aware of the competitive environment, even considering working together with other companies and organisations to bring forward solutions that can make a real difference. Solutions which address any challenges associated with health inequalities, such as demographic and geographic disparities, and show a strong commitment to contribute to the NHS carbon reduction ambitions are particularly welcomed.

SBRI: Phase 3 funding competition

Programme Ambitions

The SBRI Healthcare Phase 3 funding competition invites innovations at an advanced stage of development to accelerate their uptake into relevant health or social care settings. The aim of the competition is to facilitate the collection of evidence in real-world settings and build on the value proposition required by commissioners and regulators to make purchasing or other recommendations and decisions.

There is no shortage of innovation in the NHS or the health sector more widely. However, innovation has not diffused as quickly, or had the impact seen in other industries, particularly in reshaping how clinical services are delivered. This is despite the NHS having natural advantages over many other health systems including universal coverage of a diverse population, national standards, and relatively rich healthcare data.

Real-world validation of an innovation can accelerate its uptake and bring benefits to both industry, and health and social care by facilitating the adoption and spread of innovation. This may be achieved by providing potential adopting organisations with an understanding of the implementation pathway and assurance of benefit delivery. Alongside this, real world validation can support industry to generate investment and enhance a product's sales story to enable growth and job creation.

Accelerated Access Collaborative's ambitions

The Accelerated Access Collaborative (AAC) funds the SBRI Healthcare Programme and brings together industry, government, regulators, patients and the NHS. It removes barriers and accelerates the introduction of ground-breaking innovations which will transform care. It supports the NHS to more quickly adopt clinically- and cost-effective innovations, to ensure patients get access to the best new treatments and technologies.

The AAC ensures that research and innovation meet the needs of the public, patients and the NHS. This includes ensuring that all innovations that are adopted into the NHS can support the following targets:

- Reduce health inequalities and enhance equity of access to care through the CORE20PLUS5 initiative.
- Support the NHS ambitions to be a net zero health service through the 'Delivering a NET Zero NHS' initiative.

Core20PLUS5

NHS England launched the Core20PLUS5 initiative in 2021 and a bespoke Children and young people Core20PLUS5 in 2022 to reduce health inequalities at both the national and system level. The approach defines a target population cohort and 5 focus clinical areas requiring accelerated improvement. The Core20 are the most deprived 20% of the national population as identified by the national index of multiple deprivation while PLUS are population groups experiencing poorer than average health access, experience or outcomes which are not captured in the Core20 alone.

Delivering a net-zero NHS

The NHS strategy also includes ambitions to become the world's first net zero national health service. The "Delivering a Net Zero Health Service" report sets out the ambition and two evidence-based targets, which include:

- To reduce direct emissions (NHS Carbon Footprint) and reach net zero by 2040, with an ambition to reach an 80% reduction by 2028 to 2032.
- To reduce influenced emissions (NHS Carbon Footprint Plus) and reach net zero by 2045, with an ambition to reach an 80% reduction by 2036 to 2039.

As outlined in the LTP, sustainability commitments range from reducing single-use plastics and water consumption, through to improving air quality. The Greener NHS National Programme was formed to drive this transformation, while delivering against broader environmental health priorities.

Workforce Pressure

There is a drive in the LTP and in the UK Government's Life Sciences Vision to reduce pressure on NHS services, for instance, through driving improvements in care pathway management through technology.

The NHS is the largest employer in England, with nearly 1.2 million full-time equivalent (FTE) staff working in hospital and community services and is facing a workforce crisis. NHS hospitals, mental health services and community providers are now reporting a shortage of nearly 84,000 FTE staff, severely affecting key groups such as nurses, midwives and health visitors. General practice is also under strain with a shortage of 2,500 FTE GPs; projections suggest this gap could increase to 7,000 within five years if current trends continue. Shortages of GPs and other staff working in primary care and community services are putting ambitions to deliver more care out of hospitals at risk. Unfilled vacancies increase the pressure on staff, leading to high levels of stress, absenteeism, and turnover. This has been compounded by the Covid-19 pandemic which has exacerbated long-term issues such as chronic excessive workload, burnout and inequalities experienced by ethnic minority staff.

The NHS People Plan recognises that the NHS workforce has been under strenuous pressure since the response to COVID-19 began, and there will be further challenges ahead. Workload

remains a pressing concern calling for new ways of working and delivering care (British Association of Stroke Physician and Getting it Right Frist Time, 2019-2022).

Stroke

Background and introduction

Stroke is the second largest cause of death worldwide and fourth in the United Kingdom, with over 100,000 stroke admissions and around 35,000 stroke deaths per year (Stroke Association, 2024). The prevention, treatment and management of the illnesses and deaths caused by stroke carry vast economic consequences, not only for the healthcare system and patients but across society as a whole. For example, stroke is the major cause of acquired disability in adults, with 1.3 million stroke survivors living with disabilities in the UK and requiring support to carry out daily activities (Stroke Association, 2024). When a stroke happens in an individual of working age – estimated to be 1 case every 4 (Stroke association, 2018) – the survivor's employment prospect is reduced, leading to a further insurgence of episodes of anxiety and depression and to a loss of productivity for society.

The NHS Long Term Plan (LTP) has been set to improve the quality of its service and care of stroke patients and to reduce the loss of independent lives to stroke by early identification of at-risk patients, and the provision of support to patients to help them manage their condition. It aims to make specialist care and treatments available to more patients in a more timely and efficient manner, and further enhance the delivery of rehabilitation to improve their recovery.

The priorities identified in the NHS LTP vision are to:

- Prevent stroke by identifying and supporting people with atrial fibrillation, high blood pressure and high cholesterol, all of which increase stroke risk.
- Make sure more patients get the best treatment by:
    - Improving rapid access to appropriate brain imaging, thrombolytic (clot-busting) drugs and thrombectomy (clot extraction) treatment to help achieve the goal of ensuring all eligible patients receive thrombolysis by 2025.
    - Modernising the stroke workforce with a focus on cross-specialty and train hospital consultants from a variety of relevant disciplines to offer mechanical thrombectomy.
    - Improving the ability to deliver rehabilitation interventions recommended in clinical guidelines.
    - Increasing availability and quality of integrated community stroke rehabilitation services.
    - Enabling more stroke patients to leave hospitals earlier and receive tailored and personalised care to facilitate a good recovery at home working in partnership with voluntary organisations including the Stroke Association.
- Create new 24/7 integrated stroke care pathways across the country to make sure that patients receive high quality care and treatment sooner.

It has been observed that stroke prevalence differs according to age, sex, occupation, ethnic groups and localities and this difference has an impact on the whole stroke pathway, from

prevention and acute care to rehabilitation and the community. Globally, people of low socioeconomic status (SES) are more likely to have a stroke and have higher mortality rates and risk factors. People living in low-income countries have poorer access to stroke services and treatment, with poorer outcomes (). In England, cardiovascular diseases (including stroke and TIA) occur more frequently in people living in more deprived areas and are twice as prevalent in the most deprived areas in England than the least (Watt et al., 2022).

While clear progress has been made since the publication of the NHS LTP in 2019 and the release of the first National Stroke Service Model in 2021 – of particular note is the launch of 20 integrated stroke delivery networks (ISDNs) across England – there is still great capacity for further improvements. As the number of stroke survivors and the overall costs of stroke in the UK are expected to double in the next 20 years (Stroke Association, 2018), stroke care can still benefit from new technologies and solutions that support the population, clinicians and healthcare systems to reduce the challenges presented and generate better care outcomes.

Challenges

The challenges of dealing with stroke stem from the fact that it is a medical emergency requiring rapid diagnosis and hyperacute treatment followed by complex long-term consequences that need to be tackled at different levels and at different times after onset, often for many years.

Under this Phase 3 Funding Competition, three challenges have been identified *via* consultation with clinicians and other stakeholders working in provision of care across the spectrum and review of the James Lind Alliance Stroke Priority Setting Partnership for Stroke Research:

1) Early diagnosis
2) Rehabilitation
3) Life after stroke.

Applicants are expected to respond to one or more of the categories and should consider if their solution is specific to or can be tailored to one of the categories, whilst being mindful of the broader impact.

Emphasis should be placed on how the technology/solution will address any challenges associated with health inequalities, such as demographic and geographic disparities, and it is expected that applicants provide details on how they will address these e.g. provide details on the care pathway the intervention will affect and how it can improve this.

Challenge 1 – Early diagnosis

Most people (>95%) have their onset of stroke outside of hospital (Marshall et al., 2022), leaving the responsibility of identification and treatment of suspected strokes to ambulance

services. However, as stroke presents with a variety of symptoms that can be experienced in other conditions, prompt diagnosis and treatment are not always achieved.

There is a need for improvements in the early identification of stroke, differentiation of ischaemic from haemorrhagic stroke, identification of patients suitable for thrombectomy and exclusion of stroke mimics to ensure survival and reduce ill effects on quality of life of survivors.

Potential solutions include (but are not limited to):

- Innovations that enable a faster and timely emergency response to stroke to reduce mortality and disability, by accurate identification of potential stroke and transient ischaemic attack (TIA) patients.
- Pre-hospital validated triage tools supported by telemedicine linked to senior stroke clinicians for a timely and accurate identification of stroke due to large vessel occlusion and those patients likely to be eligible for thrombolysis/thrombectomy /rapid intracerebral haemorrhage (ICH) treatment.
- Pre-hospital validated triage tools that achieve timely and accurate identification of stroke due to ICH that benefit from early intensive blood pressure (BP) lowering.
- Remote solutions, such as video triage/telehealth, to improve connectivity and access to appropriate healthcare professionals across the whole care pathway in a timely manner.
- Diagnostics and/or apps in ambulance settings to underpin agreed clinical pathways and maintain sustainable admission levels to comprehensive and acute centres (CSC, ASC) thus maximising the proportion of acute stroke patients correctly diagnosed and taken directly to a specialist stroke centre for timely expert care and minimising or reducing the number of stroke mimics entering the stroke pathway.
- Tools to increase staff training, support workforce upskill and diminish pressure.
- Tools to ensure early, regular and inclusive communication with patients and their nominated relative or carer about diagnosis, interventions, prognosis and transfer of care plans.
- Artificial intelligence tools to improve diagnostic efficiency and accuracy and to combine information from early assessments (clinical information, neuroimaging or fluid biomarkers, patient electronic records, paramedics, carers etc.) to aid prognosis and personalised treatment decisions.

Challenge 2 – Rehabilitation

As it has been shown that greater amounts of physical therapy (dose) are associated with better recovery, and extending provision of rehabilitation interventions can lead to a significant improvement in quality of life (Marshall et al., 2022), it is paramount that rehabilitation – to a level appropriate to the medical status of the individual – be commenced early after stroke onset to achieve optimal outcomes. Multidisciplinary planning and collaboration are essential in the delivery of rehabilitation programmes, and all interventions

should be regularly monitored and evaluated using appropriate outcome measures to guide ongoing rehabilitation plans (Stroke Guideline, 2023).

There is a need for improvement in the delivery of high-intensity rehabilitation, secondary prevention, and follow-up care to improve cognitive, physical and emotional function, reduce the risk of further stroke and prevalence of secondary complications. Stroke survivors experience a wide range of different levels of disability and each have individual circumstances. The kind of specialist support needed will differ from patient to patient and needs to be personalised. Innovations need to address one or more areas including: lifestyle changes, mobility difficulties, vision deficit, speech problems, cognitive challenges and emotional disruption.

Potential solutions include (but are not limited to):

- Screening and assessment innovations to improve access to effective treatments, particularly in relation to the psychological impact of stroke, dysphasia, depression and cognition.
- Personalised interventions that support enhanced inpatient rehabilitation and integrated community stroke rehabilitation available seven days a week and at an appropriate level of intensity, empowering patient to play a key role in their recovery.
- Solutions that help the workforce to provide more rehabilitation services to stroke patients.
- Validated technologies to augment provision of a minimum of 3 hours of multidisciplinary therapy a day for as long as the patient is willing and capable of participating and showing measurable benefit from treatment, as stated in national clinical guidelines.
- Tools that enable the management of common stroke complications, including spasticity, depression, shoulder pain, central post stroke pain and venous thromboembolism.
- Apps/digital tools that provide recovery integrated feedback to patients – such as progress and personalised feedback and peer to peer support- and link these with multidisciplinary teams and patient records.
- Tools that improve the stroke rehabilitation care pathway and address any inefficiencies of health systems, for example communications between multidisciplinary teams and the patients / carers.

Challenge 3 – Life after stroke

Survivors of stroke and their families have to deal with the long-term consequences of stroke which can relate to physical, emotional and cognitive impairments that limit their activities and participation in everyday life. Supported self-care and management programmes, regular follow-ups (e.g. six-month reviews) and practical support (e.g. mobility aids, home adaptations, housing, financial support, information and transport) have been implemented in some areas to support stroke survivors. However, despite guideline recommendations, long-term stroke

management has been a neglected area in both clinical service development and research (Marshall et al., 2022).

There is a need for improvement in the quality of life of stroke survivors and the regaining of their independence and ability to participate to everyday life.

Potential solutions include (but are not limited to):

- Technologies that provide community based, personalised support and ensure people are enabled to manage their conditions as independently as possible and minimise risks of future cardiovascular events.
- Psychological and neuropsychological rehabilitation tools addressing the psychological, emotional, cognitive and neuropsychological effects commonly experienced by stroke survivors.
- Rehabilitation tools facilitating the social participation of stroke survivors, including interventions to help return to work.
- Tools that provide stroke survivors and their families access to the information they need, when they need it, about the stroke and their care.
- Educational tools to equip the health and social care workforce with specific stroke skills, both for registered and non-registered staff in specialist teams and to upskill the non-specialist workforce.

Useful Information for Applicants

Eligibility

The competition is open to any innovation (e.g., medical device, in-vitro diagnostic, digital health solutions and AI solutions, behavioural interventions, and service improvements) that meets the entry criteria and the challenges described below.

Single organisations (contracts are executed with individual legal entities) based in the UK or EU from the private, public and third sectors, including companies (large corporates and small and medium enterprises), charities, universities, and NHS Foundation Trusts, given a strong commercial strategy is provided, are eligible to apply.

Organisations based outside the UK or EU with innovations in remit for this call can apply as subcontractors of a lead UK/EU based organisation or via a UK or EU subsidiary.

Collaborations are encouraged in the form of subcontracted services as appropriate.

Innovations excluded from this competition

All proposals should also be aware that the following will be excluded:

- Basic research and innovations in the creation phase.
- Systems and solutions that will not easily integrate or communicate with NHS/community setting systems. Some evidence of interoperability and/or work to assess this will be required.
- Technologies that do not comply with GDPR policies.
- Technologies that may increase burden on the workforce.
- Wellness or wellbeing digital applications on healthy diet and/or physical exercising.
- Technologies that will exacerbate health inequalities (including digital exclusion or data inequalities) and inequity of access to care e.g., digital technologies that are inaccessible to certain communities that experience digital poverty.
- Innovations that are not co-designed with patients and end users.

Phase 3: Entry criteria

The call is open to innovations in an advanced stage of development and with the aim to accelerate these innovations into relevant health or social care settings. The aim of the call is to facilitate the collection of evidence in real-world settings and build on the value proposition required by commissioners and regulators to make purchasing or other recommendations and decisions.

To be eligible for the SBRI Healthcare Phase 3 funding competition, proposed innovations must meet the following:

- UKCA marked.
- If CE-marked only, a clear timeline to achieve UKCA mark by June 2028 for general medical devices or June 2030 for in vitro diagnostic medical devices. If regulatory approval is yet not obtained, evidence should be provided to demonstrate that the innovation is close to obtaining approval and/or in use in at least one NHS Hospital Trust.
- Clinical efficacy and safety demonstrated through an appropriate and relevant clinical evaluation.
- All projects must demonstrate relevant partnerships with a clinical partner and service(s)/clinical sites lined up.
- Projects are strongly encouraged to conduct an independent evaluation.
- For digital solutions, evidence that the technology has passed or is close to passing the necessary information governance and cyber security requirements where relevant. Evidence that the NHS England Digital Technology Assessment Criteria (DTAC) has been considered.

Desirable exit points

The aim of the funding is to generate real-world evidence to support rapid local or regional roll out of the innovation. Awarded proposals are expected to demonstrate some of the following exit points upon project completion:

- Implementation effectiveness demonstrated and a defined implementation guide produced where appropriate.
- Evidence of health and financial impact: health economics analysis (i.e., cost benefit analysis, budget impact model).
- Collation of evidence in response to NICE Early Value Assessment recommendations and related Evidence Generation Plan and/or towards full NICE guidance
- Innovation independently evaluated to demonstrate its impact in real-world settings.
- Environmental and sustainability assessment and impact.
- Equality and Health Inequalities impact assessment.
- Partnership developed for implementation in multiple sites.
- NHS Business case (e.g., procurement business cases to support transition into business-as-usual via standard commissioning routes, inclusion for national commissioning initiatives, inclusion on procurement frameworks, etc).
- Defined commissioning or procurement approach.
- Other relevant evidence to ensure local adoption following project completion, and plans for further spread and adoption (e.g., scaling-up plan and strategic plan towards adoption and spread, marketing tools development).
- Company scaling plan (e.g., staff, money, supply, etc).

Additional considerations

Please consult the Guidance for Applicants for more details.

- The programme supports innovations that plan to meet relevant regulatory standards, compliances and generate a strong evidence base. These may include CE marking, UKCA, relevant ISO certifications, etc.
- Where relevant, the NICE Digital Health Technology Framework and the Digital Technology Assessment Criteria (DTAC) should be consulted and your application should evidence your plan to meet the appropriate evidence guidelines.
- How will the proposed solution impact the care system and how will the system need to be changed (including people, processes and culture) in order to deliver system-wide benefits?
- How will you ensure that the innovation will be acceptable to patients (and their families and wider support network) and to health and social care workers?
- How will you ensure that the innovation is affordable to the NHS and wider systems such as Integrated Care Systems (ICSs) both immediately and throughout the life of the product?
- How will you ensure that the innovation enhances equity of access, such as different demographics and geographies?
- How will your innovation support the NHS commitment to reach net zero carbon?
- All proposed technologies should take into consideration appropriate integration with electronic patient records (EPR).

SBRI Healthcare Programme

This SBRI Healthcare competition is funded by the AAC in partnership with the Health Innovation Network to facilitate the collection of evidence in real-world settings and build on the value proposition of mature products for adoption and spread. The projects will be selected primarily on their potential value to the health service and social care system, and on the improved outcomes delivered for those in receipt of care.

The Phase 3 funding competition runs in one phase only and is intended to facilitate the implementation of developed innovations. Contracts will be for a maximum of 12 months and up to £500,000 (NET) per project.

The implementation will be 100% funded and suppliers for each project will be selected by an open competition process and retain the intellectual property rights (IPR) generated from the project, with certain rights of use retained by the NHS.

SBRI application process

This competition is part of the Innovate UK Contracts for Innovation, formerly known as Small Business Research Initiative (SBRI) programme, which offers innovative organisations the chance to work directly with the public sector to solve complex challenges:

- It enables government departments and public sector agencies to procure new technologies faster and with managed risk.
- It provides vital funding for a critical stage of technology development and evidence gathering through demonstration and trial.

The SBRI scheme is particularly suited to small and medium-sized businesses, as the contracts are of relatively small value and operate on short timescales for Government departments. Thus, it is an opportunity for new companies to engage a public sector customer pre-procurement.

For more information about Contracts for Innovation, visit: Contracts for Innovation - Innovate UK Business Connect (ktn-uk.org).

The SBRI Healthcare is managed on behalf of NHS England by LGC Group. All applications should be made using the application portal which can be accessed through the Research Management System. Applicants are invited to consult the Invitation to Tender, the Guidance for Applicants, the RMS portal Guidance and FAQ pages on the SBRI Healthcare website to help prepare their proposal.

A briefing event for organisations interested in finding out more about the competition and a webinar event to respond to potential applicants' questions will be held. Please check the SBRI Healthcare website and/or SBRI Healthcare LinkedIn page for confirmation of dates,

information on how to register, and details of the competition, along with attending supporting webinars and Q&A sessions.

Key dates

Competition launch	31 July 2024
Deadline for applications	18 September 2024 **(13:00 BST)**
Interview Panel	December 2024
Project start	January - February 2025

More information

For more information on this competition, visit: https://sbrihealthcare.co.uk/

For any enquiries e-mail: sbri@LGCGroup.com

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