All information regarding future IHI Call topics is indicative and subject to change. Final information about future IHI Calls will be communicated after approval by the IHI Governing Board.

Topic 3: Improved prediction, detection, and treatment approaches for comprehensive stroke management

Expected impacts to be achieved by this topic

- Patients will be offered accelerated access to the healthcare system through improved and holistic management of stroke including prevention, diagnosis, treatment, and rehabilitation that will lead to better outcomes for their health.
- Development of advanced visualisation approaches, connected artificial intelligence (AI)-based devices and modelling-based systems supporting health research and innovation (R&I), resulting in wider availability of personalised health interventions to end-users.
- Medical technology, pharmaceutical and biotechnology companies develop and offer integrated, advanced solutions for prevention, diagnosis, and treatment of stroke. This will facilitate coordinated decision-making by the different healthcare professionals involved in the stroke care pathway.
- Better implementation and scale up of existing treatments that have proven to be effective, ensuring wide coverage of the right treatment options for patients at the right time; also avoiding disparities in countries and regions.
- Contribute to the EC proposal for an 'European Health Data Space' (EHDS) by promoting better exchange of, and access to, different types of health data and data generated by health technologies.

Expected outcomes

Research and innovation (R&I) actions (projects) to be supported under this topic must aim to deliver results that contribute to all the following expected outcomes.

- Patients will benefit from superior healthcare compared to the current standard of care through the availability of a clear pathway for prevention, diagnosis, and treatment of their stroke. This should be achieved by early and rapid diagnosis of stroke, more integrated and precise interventions, and treatment strategies with the patient in the centre.
- Healthcare professionals will have access to integrated patients' health data, improved visualisation, predictive computational models and clinical support decision systems for stroke, and benefit from efficient coordination among and within stages of care and clinical specialities.
- Healthcare systems will benefit from more effective organisation of stroke management and personalisation of care delivery. This will increase treatment and care effectiveness and efficiency.
- Researchers will benefit from access to integrated data, innovative modelling-based tools, and a more
 patient-centred definition of clinical outcomes after stroke (including patient reported outcome
 measurement and patient reported experience measurement), which will facilitate the continued
 improvement and development of future intervention strategies.

 Health care systems, researchers, and industry will benefit from new innovative modelling tools enabling integration and analysis of a wider, actionable range of patient-specific data, including federated analysis of data.

Scope

Globally, stroke is the second leading cause of death and the third leading cause of disability. One in four people are in danger of stroke in their lifetime¹.

In Europe in 2017, nearly 1.5 million people suffered a stroke, nine million Europeans lived with a stroke, and more than 430,000 people died due to a stroke. The total cost of stroke in that year was €60 billion. The number of new strokes and the number of people living with stroke is set to rise due to the ageing population of Europe, as age is the greatest, non-modifiable risk factor for stroke².

Stroke is a heterogeneous, multifactorial disease regulated by non-modifiable (e.g., age, sex, family history) and modifiable risk factors (e.g., high density lipid-cholesterol, low density lipid-cholesterol, cigarette smoking) and underlying pathologies (such as diabetes, hypertension, atrial fibrillation) and as such, it requires a multi-factorial approach³. However, stroke is a preventable, treatable, and manageable disease and thus the potential to reduce its burden and its long-term consequences exists⁴.

The challenge in stroke management is the lack of efficient and comprehensive pathways along the whole continuum of the disease – including the variation of structural settings depending on the location of the patient (rural vs. central) and between countries. While several effective treatment approaches are available, there are still silos existing between the different stages of care (e.g., primary, acute care, intensive care, chronic hospitalisation, rehabilitation). The implementation of connected healthcare pathways will lead to an improvement in the outcome for the patients and thereby drive efficiency and effectiveness from a clinical and health resource perspective.

Better communication, sharing and integration of data along the whole stroke care pathway has the potential to be a game changer for stroke patients and for the healthcare professionals as well as payers.

Integrating data is key to allow for modelling, artificial intelligence (AI) and machine learning (ML)-based evaluation to identify groups and individual persons at risk and assure early recognition of stroke, thereby providing faster diagnosis and optimal, patient-specific treatment, resulting in better outcomes for patients. Effective, personalised and rapid care is critical and can make a substantial difference between full recovery and possible permanent impairment or death.

Moreover, comprehensive stroke management continues in the post-acute treatment setting and includes long-term follow-up for secondary prevention and rehabilitation. This is important, as a high percentage of patients are readmitted to the hospital or suffer a second stroke. More than a quarter of patients do not adhere to medication and/or have their blood pressure controlled. Patients frequently report that post-stroke follow up is impaired by siloed data between their generalist and specialist care.

Innovative solutions for faster acquisition, integration, and better retention of multiple types of data and better organisation among the various actors across the entire stroke pathway are crucial to achieve optimal prevention and treatment focused on the needs of patients. Use of novel technologies for federated data analytics and interpretation could help in this direction and assist in providing the right treatment to patients in a timely manner, improving their outcomes.

 ¹ Feigin VL et al. World Stroke Organisation (WSO): Global Stroke Fact Sheet 2022. International Journal of Stroke, 2022;17(1):18–29.
 ² The Economic Impact of Stroke – SAFE (Stroke Alliance Sor Europe) <u>https://www.safestroke.eu/wp-content/uploads/2020/10/03.-</u> <u>At What Cost EIOS Full Report.pdf</u>

³ Goldstein LB et al. Primary Prevention of Ischemic Stroke. Stroke, 2006;37:1583-1633.

⁴ Norrving B et al. Action Plan for Stroke in Europe 2018-2030. European Stroke Journal, 2018;3(4):309-336.

Applicants to this topic should address all the aims below in their proposals.

- Develop approaches to integrate patient-relevant health data, from primary care / outpatient clinic, hospital, and rehabilitation settings, as relevant, improving data retention along the care pathway. Applicants could consider starting with a focus on patients at higher risk with the possibility to expand to other patients.
- Develop a next generation of systems that promote interoperability of data from different settings (including intensive and acute care units) and support better clinical decision making. Strategic approaches for integration with the EHDS and community-based, collaborative integrated care should be considered.
- Create solutions to foster better access to data for all involved healthcare professionals (primary care, hospital care and after hospital release e.g., rehabilitation) and support exchange of knowledge and information between the different actors – including at the level of algorithms and datasets that can be exchanged under ethically and legally sound conditions.
- Develop innovative tools and approaches, for example 'virtual human twin' model approaches and AI/ML for enhanced computational modelling, optimised for transparency to users and non-users, federated data analytics, and visualisation for enhanced output/results view and interpretation. These tools aim at appropriate risk stratification, timely prediction of stroke and stroke recurrence, faster diagnosis, and treatment.
- Propose innovative approaches to improve and expedite diagnostic and treatment decisions for streamlining operations and guiding patients in the continuum of stroke care in a patient-centric way. This should include consideration of the complexity of the organisational dimension.
- Propose approaches to improve implementation and scale-up of treatment in Europe relying on multimodal clinical data capture and their better interpretation and use in patient management and clinical decision-making. This should include consideration of the regional differences in stroke management and access to treatment options across Europe.
- Propose approaches to enhance precision of care delivery as well as improving patient experience and quality of life using new technologies, tools, and educational means (e.g., education on identification of risk factors, signs of stroke, treatment adherence).

Why the expected outcomes can only be achieved by an IHI project

This topic requires cross-sectorial collaboration, including contributions from all the different healthcare professionals, health data specialists, patients and their care network, academia, as well as the different industry sectors, including medical technology (e.g., focusing on connected care and medical devices) and pharma sector (providing pharmaceutical interventions for stroke). Such a cross-sectional public-private partnership is needed to break the silos in care, bring the necessary diverse expertise together and combine different types of resources to address the challenge of delivering an efficient and comprehensive stroke management focused on patients' needs.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 40 000 000.

IHI estimates that an IHI financial contribution of between EUR 10 000 000 and 13 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia should ensure that at least 45% of the action's eligible costs and costs for action-related additional activities are provided by contributions [In-kind contributions to operational activities (IKOP), financial contributions (FC), in-kind contributions to additional activities (IKAA)] from private members and/or contributing partners and the constituent or affiliated entities of the private members and/or of the contributing partners. Contributing partners may not contribute IKAA (see call conditions for further information).

Indicative duration of the actions

Applicants should propose a project duration such that it matches project activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and calls management rules under "Specific conditions on availability, accessibility and affordability" apply.