

Implementation strategy for stroke care measurement

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Implementation Strategy Objectives and Specific Aims

The main objective is to implement a strategy for stroke care measurement in Eastern European and Central Asian countries. This strategy will be centered around the creation of an international registry focusing on the quality of stroke treatment. This registry aims to:

- 1. Providing insights into the current state of stroke treatment** delivery in these regions, evaluated against a universally accepted set of metrics. This information will act as a benchmark for future initiatives.
- 2. Identifying existing gaps in stroke care delivery.** By comparing data across diverse geographical, political, and socio-economic boundaries, we can identify barriers to the implementation of best-practice interventions.
- 3. Establishing a solid evidence base** for the development of new stroke care implementation initiatives. This includes proposing healthcare policy recommendations at both national and international levels.
- 4. Assessing the impact of external stroke care interventions.** As the registry is non-interventional and only intended to collect, analyze, and evaluate information from routine clinical practice, it can be used as a tool to measure the effectiveness of various interventions.

Background and Significance

While effective stroke care interventions that significantly improve patient outcomes are well-documented, their application in everyday clinical practice often falls short. Preliminary data and self-reported information suggest significant variation in stroke treatment delivery within and between countries in Eastern Europe and Central Asia. However, there is a lack of substantial data to identify specific areas of deficiency, or to provide standardized benchmarks for quality of care.

The data collected through this implementation strategy will facilitate a retrospective analysis to evaluate existing stroke care quality and provide a robust evidence base for future interventions.

RES-Q was initially developed as a project of ESO EAST (European Stroke Organization Enhancing and Accelerating Stroke Treatment) to provide an accessible, free to use platform for quality monitoring. Thanks to the IRENE project and experts involved the implementation strategy for stroke care measurement was created and is being implemented. Group of target countries comprised 23 countries from primarily Eastern Europe and Central Asia. Participation in RES-Q is voluntary, and no remuneration is provided.

Research Methodology

Participation in RES-Q is limited to submission of patient treatment information to the registry, and subsequent use of this information for retrospective research studies targeted at improving the quality of stroke care, and improvements in patient outcomes. The only selection criteria for hospital participation in RES-Q is that the hospital admits stroke patients, or patients suspected of having a stroke.

- 1. Patient data submitted to the registry will be stored electronically and will follow a strict policy of data minimization.** The only potentially identifiable metrics collected are currently limited to age and sex in order to provide basic demographic information. No other identifiable information will be collected in the registry, and all patients will be assigned a generated identification number specific only to RES-Q.
 - a. Only patients diagnosed with stroke or admitted with suspicion of stroke should have their data entered in the registry. This includes patients evaluated and/or treated for ischemic stroke, intracerebral hemorrhage, subarachnoid hemorrhage, cerebral venous thrombosis, or clinically defined transient ischemic attack (TIA).
 - b. Patients must be entered for at least one month per year, or for a minimum of 30 consecutive patients, whichever is greater. Patients entered to the registry must be consecutive by admission date and must not be selected based on any other criteria beyond those specified in point a. above. Patients may be entered in excess of the minimal requirements; however, they must be entered consecutively based on a predefined time period, in order to minimize selection bias.
- 2. The Principal Investigator of RES-Q and the RES-Q management group must approve all retrospective research projects which will involve the use of medical information entered in the registry.** This approval must be obtained prior to access to the registry data being granted and will be assessed based on scientific quality and validity. Evidence of research ethics committee approval must also be provided with any request. All access to medical data in the registry will be documented.
 - a. Stored data will only be accessible by the managing RES-Q researchers, users from the site which originally submitted the data, external parties specifically authorized by the submitting sites, and researchers approved by the RES-Q management group.
 - b. Data is expected to be stored in perpetuity, or until such time as it is no longer deemed to be valuable to the stated purpose of improving the quality of stroke care.
- 3. Patients whose data has been submitted to RES-Q will not be contacted, nor will they be notified of the results of research conducted based on their medical information.**
 - a. Informed consent from patients from the European Union whose medical data is entered to RES-Q is not required pursuant to Regulation (EU) 2016/679 General Data Protection Regulation (GDPR). Data collected in RES-Q is collected on the legal bases of legitimate interest and public interest, as specified in Article 6.1(e&f) and Article 9.2(h,i, &j)
 - b. Hospitals contributing data from outside the European Union are expected to comply with their own regional and national laws and regulations regarding patient privacy and data protection.

Statistical Considerations and Reporting

As RES-Q is not hypothesis driven, no formal prospective calculations of sample size have been conducted or provided here. However, we will conduct periodic assessments of data validity based on known population sizes, expected incidence rates, and external reporting of stroke quality of care.

The RES-Q management group will generate regular reports of aggregated data at a site level, national level, and international level. These reports will include site specific aggregate results along with national and international benchmarks for all collected metrics. The calculations used in deriving the aggregated results will be part of a statistical analysis plan (SAP) developed by the RES-Q management group and can be requested by participating hospitals at any time.

Aggregate statistical analyses generated as part of the regular reporting are done in accordance with the research methodology described above. Hospitals which do not meet the required minimum participation of 1 month or 30 consecutive patients (whichever is greater), will be excluded from the analysis for the specified time period.

Strategy for Stroke Care Measurement Implementation Steps

To effectively roll out this project in Eastern Europe and Central Asia, a well-defined implementation strategy is imperative. The strategy will focus on engaging with stakeholders, building capacity, collecting and analyzing data, making policy recommendations based on the findings, and evaluating the impact of these interventions.

The following is a detailed implementation strategy for Stroke Care Measurement:

- 1. Recognition of Target Countries:** The initial stage of implementing this strategy involves acknowledging the target countries in Eastern Europe and Central Asia. These countries, which have been pre-identified as the ESO EAST countries, will form the primary area of focus for the RES-Q.
- 2. Stakeholder Engagement:** Engage with key stakeholders in each of these countries. These may include healthcare professionals, government healthcare officials, and patient advocacy groups. These stakeholders will play a crucial role in the collection and reporting of data, as well as the dissemination and implementation of best practices.
- 3. Training and Capacity Building:** Conduct training sessions for healthcare professionals in these countries on the RES-Q protocol. This will ensure that all involved parties are on the same page in terms of data collection methods, benchmarks, and quality standards. Capacity building initiatives will also be crucial for enabling these countries to effectively collect and report data.
- 4. Data Collection:** Encourage voluntary participation in data collection efforts. Stakeholders will be asked to collect data on stroke treatment delivery in their respective countries according to the RES-Q protocol. This will include data on patient outcomes, treatment methods, and adherence to international guidelines.
- 5. Data Analysis:** Once the data has been collected, it will be analyzed to identify any gaps in stroke care delivery. This will provide a clear picture of the current state of stroke care in these countries, and highlight areas where improvements can be made.
- 6. Continual Monitoring and Improvement:** After the implementation and evaluation phases, continual monitoring will be necessary to ensure that improvements are sustained and to identify any new areas of concern. The RES-Q protocol will also be regularly updated to reflect new research findings and changes in international guidelines.

As participation in the registry does not represent any physical risk to the patient, there is no exclusion criteria specifically related to risk. The racial, gender, and ethnic characteristics of patients entered in the registry will represent the demographics of patients seeking stroke treatment, as patients entered to the registry should be consecutive according to admission date with no other selection criteria. No patients shall be excluded based on race, ethnicity, or gender.

Potential Risks

There are no physical risks to patients based on participation in RES-Q. There is potential risk of breach of data confidentiality and associated patient privacy. These risks will be minimized by:

1. Strict data minimization; only age and gender are collected as demographic information.
2. A unique identifier is assigned to patients in RES-Q, no linkage key is kept unless the contributing site wishes to maintain their own separate key at their own location.
3. All access to the registry and any modification of data is logged, and access is limited by user role.
4. Access to the registry for researchers or external parties must be approved and routinely reviewed by the Principal Investigator for RES-Q.
5. The registry and associated research database are physically housed within the secure hospital infrastructure of St. Anne's University Hospital Brno, in Brno, Czech Republic.

Potential Benefits

The implementation of strategy for stroke care measurement in Eastern Europe and Central Asia holds several potential benefits.

Firstly, it will provide a clear picture of the current state of stroke care in these regions. By collecting and analysing data according to internationally accepted metrics, we will gain insight into the effectiveness of current practices and identify areas for improvement. This will serve as a baseline for future initiatives and interventions.

Secondly, it will allow for the identification and understanding of gaps in stroke care. Understanding these gaps is the first step towards bridging them and ensuring uniform, high-quality care across different regions.

Thirdly, the RES-Q will provide an evidence base for policy decisions. By demonstrating the current state of stroke care, it can influence both national and international healthcare policies, leading to more effective and efficient allocation of resources.

Moreover, it will enable the evaluation of the impact of different stroke care interventions. By monitoring changes over time, we can assess the effectiveness of various interventions and adjust them as necessary.

By striving to enhance the quality of stroke care, we can potentially reduce the morbidity and mortality associated with strokes, improving the quality of life for patients across Eastern Europe and Central Asia.



Costs and Payments

All costs associated with operating and maintaining the registry will be the responsibility of the RES-Q management group with support from the European Stroke Organization. There is no required financial contribution from participating hospitals or health regions, and no cost will be incurred by participants or their healthcare providers. Patients and participating hospitals will not be remunerated for their participation in RES-Q.

Appendix A – RES-Q Questionnaire (v2.0 – Updated Mar.23rd, 2021)

RES-Q Data Collection Form – 2021 update

ADD PATIENT

Study Subject ID:	#####
Enrollment Date:	DD-MM-YYYY
Study:	QR-ESO-EAST

ADMISSION DETAILS

Age:	<input type="text" value="years"/>	Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female
Last seen normal date:	<input type="text" value="DD-MM-YYYY"/>	Last seen normal time:	<input type="text" value="HH:MM"/>
Date of admission to the first hospital:	<input type="text" value="DD-MM-YYYY"/>	Time of admission to the first hospital:	<input type="text" value="HH:MM"/>
Stroke in the hospital:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not known	Recurrent stroke:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not known

HOSPITALIZATION DETAILS

Department type:	<input type="checkbox"/> neurology <input type="checkbox"/> neurosurgery <input type="checkbox"/> anesthesiology/resuscitation/critical care department <input type="checkbox"/> internal medicine <input type="checkbox"/> geriatrics <input type="checkbox"/> other		
The patient was hospitalized in:	<input type="checkbox"/> Stroke unit / ICU <input type="checkbox"/> Other monitored	The patient was assessed for rehabilitation needs by PT/OT/ST within the first 72 hours after the admission to the hospital:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not known

bed
(telemetry)

Standard bed

Stroke unit: A patient is hospitalized in a stroke unit, if they are admitted in a specialized bed where the patient is monitored, at minimum, for blood pressure, heart rate, oxygen saturation, and EKG.

Stroke type:

- Ischemic stroke
- Intracerebral hemorrhage
- Transient ischemic attack - TIA
- Subarachnoid hemorrhage
- Venous thrombosis
- Undetermined

Stroke type: Add patients diagnosed under the following codes:

- I60 Subarachnoid haemorrhage;
- I61 Intracerebral haemorrhage;
- I62 Other nontraumatic intracranial haemorrhage;
- I63 Cerebral infarction;
- I64 Stroke, not specified as haemorrhage or infarction;
- I67.7 Cerebral arteritis, not elsewhere classified;
- G08 Intracranial and intraspinal phlebitis and thrombophlebitis;
- G45 Transient cerebral ischaemic attacks and related syndromes.

STROKE TYPE: ISCHEMIC STROKE

Level of consciousness
on admission:

- Alert
- Drowsy
- Comatose
- Glasgow coma scale
(GCS)
- Unknown

Glasgow coma scale
(GCS):

- 15 - 13
- 12 - 8
- < 8

NIHSS on admission:

- Not performed
- Performed
- Not known

Score:

Head CT / MRI:

- Not performed
- Performed
- Not known

Time performed:

- Within 1 hour after
admission
- Later than 1 hour
after admission

Was patient put on a
ventilator?

- Yes
- No
- Not known

Recanalization procedures:

- Not done – primary centre / comprehensive centre
- IV tPa – primary centre / comprehensive centre
- IV tPa + endovascular treatment – comprehensive centre
- Endovascular treatment alone – comprehensive centre
- IV tPa + referred to another centre for endovascular treatment –
primary centre

- Referred to another centre for endovascular treatment – primary centre
- Patient referred to another centre for endovascular treatment and hospitalization continues at the referred to centre – comprehensive centre
- Patient referred for endovascular treatment and patient is returned to the initial centre – primary centre
- Patient was returned to the initial centre after recanalization procedures were performed at another centre

RECANALIZATION PROCEDURES: IV tPa (door to needle or bolus time)

Door to needle time:	<input type="text" value="minutes"/>	Admission time:	<input type="text" value="HH:MM"/>
		Bolus time:	<input type="text" value="HH:MM"/>

RECANALIZATION PROCEDURES: IV tPa + endovascular treatment (door to needle or bolus time)

Door to needle time:	<input type="text" value="minutes"/>	Admission time:	<input type="text" value="HH:MM"/>
Door to groin puncture time:	<input type="text" value="minutes"/>	Bolus time:	<input type="text" value="HH:MM"/>
		Groin puncture time:	<input type="text" value="HH:MM"/>

RECANALIZATION PROCEDURES: Endovascular treatment alone

Door to groin puncture time:	<input type="text" value="minutes"/>	Admission time:	<input type="text" value="HH:MM"/>
		Groin puncture time:	<input type="text" value="HH:MM"/>

RECANALIZATION PROCEDURES: IV tPa + referred to another center for endovascular treatment (door to needle or bolus time)

Door to needle time:	<input type="text" value="minutes"/>	Admission time:	<input type="text" value="HH:MM"/>
Door in - door out time:	<input type="text" value="minutes"/>	Bolus time:	<input type="text" value="HH:MM"/>
		Discharge time:	<input type="text" value="HH:MM"/>

RECANALIZATION PROCEDURES: Referred to another centre for endovascular treatment – primary centre

Door in - door out time:	<input type="text" value="minutes"/>	Admission time:	<input type="text" value="HH:MM"/>
		Discharge time:	<input type="text" value="HH:MM"/>

RECANALIZATION PROCEDURES: Patient referred to another centre for endovascular treatment and hospitalization continues at the referred to centre – comprehensive centre

Door in - door out time:	<input type="text" value="minutes"/>	Admission time:	<input type="text" value="HH:MM"/>
		Discharge time:	<input type="text" value="HH:MM"/>

RECANALIZATION PROCEDURES: Patient referred for endovascular treatment and patient is returned to the initial centre – primary centre

<input type="text" value="minutes"/>	Admission time:	<input type="text" value="HH:MM"/>
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Door in - door out time:

Discharge time:

HH:MM

END OF RECANALIZATION PROCEDURES

Dysphagia screening:

- Yes, Guss test
- Yes, other
- Was performed at another centre
- No
- Patient could not be tested (intubated)
- Not known

Time performed:

- within the first 24 hours after admission to the hospital
- after the first 24 hours after admission to the hospital

Atrial fibrillation / flutter:

- Known aFib
- Newly-detected at admission
- Detected during hospitalization
- Not detected
- Not known

Method of detection:

- Telemetry with monitor allowing automatic detection of aFib
- Telemetry without monitor allowing automatic detection of aFib
- Holter-type monitoring
- EKG monitoring in an ICU bed with automatic detection of aFib
- EKG monitoring in an ICU bed without automatic detection of aFib

Was ambulatory heart rhythm monitoring recommended?

- Yes
- No

Carotid arteries imaging within 7 calendar days after admission to the hospital:

- Yes
- No
- Not known

Was decompressive craniectomy performed?

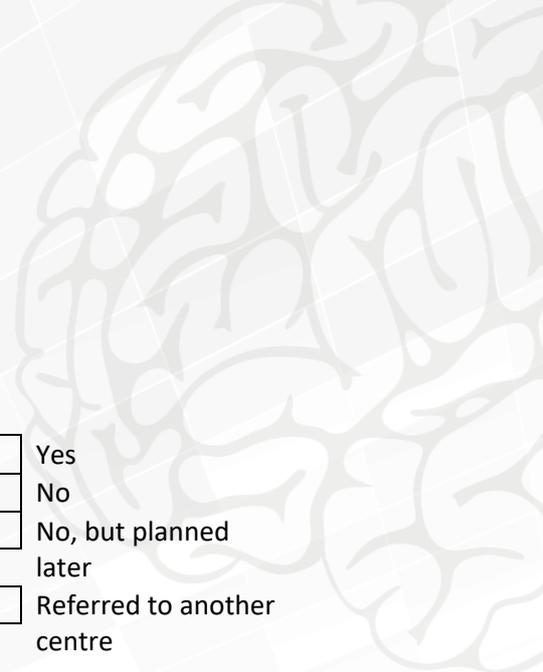
- Yes
- No
- Referred to another centre

Which antithrombotic medication was prescribed on discharge?

- antiplatelets
- Vitamin K Antagonist
- dabigatran
- rivaroxaban
- apixaban
- edoxaban
- LMWH or heparin in prophylactic dose
- LMWH or heparin in full anticoagulant dose
- Not prescribed, but recommended
- nothing

Was the patient discharged on a statin?

- Yes
- No



Was antihypertensive medication prescribed on discharge?

Not known
 Yes
 No
 Not known

Symptomatic carotid stenosis:

50% - 70%
 > 70%
 No
 Not known

Was carotid endarterectomy or angioplasty/stenting done within first two weeks after the stroke onset?

Yes
 No
 No, but planned later
 Referred to another centre

STROKE TYPE: INTRACEREBRAL HEMORRHAGE

- Level of consciousness on admission
- NIHSS on admission
- Head CT / MRI
- Dysphagia screening

Vascular imaging:

CTA
 MRA
 DSA
 None

Was the patient placed on a ventilator?

Yes
 No
 Not known

Was neurosurgery performed?

Yes
 No
 Not known

If neurosurgery was performed, select the type:

Intracranial hematoma evacuation
 External ventricular drainage
 Decompressive craniectomy
 Referred to another centre

The reason for bleeding was:

arterial hypertension
 aneurysm
 arterio-venous malformation
 anticoagulation therapy
 amyloid angiopathy
 Other / not known

STROKE TYPE: TIA

- Head CT / MRI
- Atrial fibrillation / flutter
- Carotid arteries imaging
- Antithrombotic medication
- Discharged on a statin
- Endarterectomy or angioplasty for carotid stenosis

STROKE TYPE: SUBARRACHNOID HEMORRHAGE

- Level of consciousness on admission
- Vascular imaging

The reason for bleeding was known: Yes
 No

Intervention: Endovascular (coiling)
 Neurosurgical (clipping)
 Other neurosurgical treatment (decompression, drainage)
 Patient referred to another hospital for intervention
 No intervention

STROKE TYPE: VENOUS THROMBOSIS

- Level of consciousness on admission
- NIHSS on admission
- Head CT / MRI
- Ventilator
- Dysphagia screening
- Antithrombotic treatment

Treatment: Anticoagulation
 Endovascular intervention - thrombectomy
 Endovascular intervention – local thrombolysis
 Neurosurgical treatment (decompressive craniectomy)

DISCHARGE

If the patient is a smoker, was he recommended to a smoking cessation program? Yes
 No
 Not a smoker

Was the patient recommended to see a cerebrovascular expert? Recommended, and appointment was made
 Recommended, but the appointment was not made
 Not recommended

Was antihypertensive medication prescribed at discharge? Yes
 No
 Not known

Discharge destination: Home
 Transferred within the same centre
 Transferred to another centre
 Social care facility
 Dead

Department transferred to within the same centre: Acute rehabilitation

Type of centre transferred to: Stroke centre
 Comprehensive stroke centre

Long-term care bed
 Another hospital
 Another department

Type of department transferred to within another centre:

Acute rehabilitation
 Long-term care bed
 Neurology
 Another department

Functional status (mRS) on discharge (see notes at the end of the document).

Date of discharge:

FUNCTIONAL STATUS (MRS) ON DISCHARGE

0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability, unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention

If mRs is UNKNOWN derive from following algorithm (questions **a** to **e**):

a) Can the patient walk on their own? If No go to question **b**
 If Yes go to question **c**

b) If the patient can't walk on their own can they walk if someone is helping them? If Yes score 4
 If No score 5

c) If the patient can walk on their own (includes walking aids) do they need help with simple personal activities (toilet, bathing, dressing, cooking, household tasks, simple finances)? If Yes score 3
 If No go to question **d**

d) If they can perform simple personal activities does he need help with more complex usual activities (driving, golf, finances, household bills, work tasks)? If Yes score 2
 If No go to question **e**

e) If they have no disability do they have any symptoms?

<input type="checkbox"/>
<input type="checkbox"/>

If Yes score 1

If No score 0