Deliverable no. D1.1.1 Glossary of variables for the ICTUSnet registry

WP 1 Development of regional registries and ICTUSnet platform

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Deliverable description:
The following deliverable includes a list of variables that seek to obtain the information necessary to work out a series of indicators/metrics, some of which from the aforementioned consensus document. This proposal (54 variables) has been thoroughly discussed with the rest of the beneficiaries of the ICTUSnet project and a consensus was reached after the second ICTUSnet meeting held in Montpellier (September 20-21, 2018).

Revision history			
Version	**Date**	**Comments**	**Partner**
1	25/07/2018	FMS proposed to clarify indicator 3, 6 and 9. They proposed to add to the list of variables anticoagulation therapy and consider to collect cardiovascular risk factors as mandatory variables ARNS proposed to add Door to needle and Symptoms to door as new indicators, consider to collect more information regarding EVT (type of device, use of balloon catheter) and adding smoking to cardiovascular risk factor IACS had doubts about definitions (time-event), mRS assessment, indicator 9 IdisBa was concerned about obtaining some variables such as initial mTICI score, ASPECTS, time of first imaging, distal embolizations	FMS, ARNS, IACS, IdISBa
2	17/09/2018	To be discussed in Montpellier meeting	AQuAS
3	27/09/2018	Final decision on type of variable (minimum set or recommendable) FMS, IdisBa and ARNS proposed to add some new variables	IACS, IdISBa, FMS, ARNS
4	11/10/2018	Final draft and list of variables	All

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ABBREVIATIONS AND ACRONYMS

EVT	Endovascular treatment
WP	Work package
mTICI	modified thrombolysis in cerebral infarction
mRS	Modified Rankin scale
SICH	Symptomatic intracranial haemorrhage
IVT	Intravenous thrombolysis
PSC	Primary Stroke Center
CSC	Comprehensive Stroke Center
NIHSS	National Institutes of Health Stroke Scale

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1. EXECUTIVE SUMMARY

The consensus variables initially shared in the ICTUSnet registry will be those related to the reperfusion treatment in acute ischemic stroke, mainly endovascular treatment (EVT).
The recent publication (1) of the consensus document of different scientific societies to improve the quality of EVT in acute ischemic stroke includes indicators with their respective definitions and descriptions to facilitate the determination of quality standards through their comparison between different Centers.
The following deliverable includes a list of variables that seek to obtain the information necessary to work out a series of indicators/metrics, some of which from the aforementioned consensus document. This proposal (54 variables) has been thoroughly discussed with the rest of the beneficiaries of the ICTUSnet project and a consensus was reached after the second ICTUSnet meeting held in Montpellier (September 20-21, 2018).
In addition, these indicators/metrics will be used in WP 3 to evaluate EVT in the assessment of the acute phase of the stroke patient.
Those issues related to the different levels of interoperability needed to build the common database will be described in the deliverable related to task 1.3.

2. DEFINITIONS

Ischemic central nervous system infarction (2).—A uniformly accepted simple definition of central nervous system infarction remains elusive. A successful multidisciplinary attempt arrived at a definition as follows, according to the document published by the Multisociety Consensus Quality Improvement Revised Consensus Statement for Endovascular Therapy of Acute Ischemic Stroke: Central nervous system infarction is defined as brain, spinal cord, or retinal cell death due to ischemia, based on:

1. Pathological, imaging, or other objective evidence of cerebral, spinal cord, or retinal focal ischemic injury in a defined vascular distribution;

or

2. Clinical evidence of cerebral, spinal cord, or retinal focal ischemic injury based on symptoms persisting at least 24 hours or until death, and other etiologies excluded.

Door-to-event time.—the term "door" is defined as the time of arrival (admission) at the emergency department for an outpatient or for inpatients (hospitalized because of a condition other than stroke) the time when he is discovered to have a stroke. Event can be defined as imaging or treatment.

Successful revascularization.—Successful revascularization is considered to represent modified thrombolysis in cerebral infarction (mTICI) grade = or > 2b through the previously occluded vessel segment (Table 1).

Symptomatic intracranial hemorrhage.—Symptomatic intracranial hemorrhage (SICH) is a parenchymal hematoma type II (Safe Implementation of Thrombolysis in Stroke Monitoring Study [SITSMOST] definition) or subarachnoid hemorrhage (SAH) with neurologic deterioration leading to an increase in National Institutes of Health Stroke Scale (NIHSS) score > 4 or leading to death within 36 hours of treatment. Because of the risk of vessel perforation during endovascular procedures, SAH is added as a cause of intracranial hemorrhage to the SITS-MOST SICH definition (Multisociety Consensus recommendation).

Good clinical outcome.— Good clinical outcome is a measure of function (as assessed at 3 months by a modified Rankin scale, mRS, 0-2; Table 2). This does not exclude clinically significant benefit in patients in whom a mRS score of 2 is not achieved. Assessment of the mRS can be performed face to face or by a phone call (following an structure and validated interview to correctly scored functional status).

3. SELECTION OF THE COHORT

As the ICTUSnet registry will include those variables related to reperfusion therapy, the cohort of interest will be formed by those patients with the diagnostic of acute ischemic stroke (AIS). During the Montpellier meeting, the group discussed that in some circumstances, patients with an initial diagnosis of transient ischemic attack and a large vessel occlusion could be included as long as they get worse after TIA diagnosis. As it is expected that asymptomatic patients will not be treated, we consider these patients as AIS patients.

The group agreed that since inclusion of all patients undergoing any type of reperfusion therapies (isolated intravenous thrombolysis- IVT-, IVT plus EVT-bridging-, primary EVT) is difficult because it would need the commitment of all treating hospitals in each region involved in the ICTUSnet project, only patients that undergo EVT will be finally included in the central platform. *That is, primary EVT and bridging* procedures. As bridging procedures include cases that receive IVT prior to EVT, we will collect variables related to IVT procedure, but only in those selected cases.

4. INDICATORS/METRICS

4.1. Process indicators/metrics

Indicator 1: % of patients with the required (mandatory) data entered in the registry

Definition: percentage of patients in whom information has been entered in the all the mandatory set of variables

Calculation: (number of patients in whom mandatory variables are filled in / number of patients entered in the registry) * 100

Metric 1: 100% of the patients have all the required data entered in the registry.

Indicator 2: Symptoms to door

Definition: time from symptoms onset (or last time seen well) to Comprehensive Stroke Centre (CSC) arrival.

Calculation: ddmmyyyy/ hh:mm arrival (= hospital admission) – ddmmyyyy/ hh:mm symptoms onset (or last time seen well)

Metric 2: To achieve median times from stroke onset to CSC arrival of 180 minutes.

Indicator 3: Door to puncture

Definition: time from CSC arrival to groin puncture.

Calculation: ddmmyyyy/hh:mm groin puncture - ddmmyyyy/hh:mm CSC arrival

Metric 3:
For all patients undergoing EVT at the CSC: 50% of patients should have a CSC door to puncture < or = 90 minutes.
For transferred-in patients without 2nd neuroimaging at CSC: 75% of patients should have a CSC door to puncture time < or = 80 minutes.

Indicator 4: Imaging to puncture
Definition: time from 1st neuroimaging (either at PSC or CSC) to arterial puncture for the endovascular procedure.
Calculation: ddmmyyyy/HH: MM 1st neuroimaging - ddmmyyyy/HH: MM arterial puncture (result in minutes)
Metric 4: 75% of EVT patients should have a 1st neuroimaging to puncture time < or = 110 minutes.

Indicator 5: Door to needle time
Definition: time from arrival at the IVT treating Center (either PSC or CSC) to needle (bolus of alteplase/tenecteplase).
Calculation: ddmmyyyy/HH: MM bolus onset - ddmmyyyy/HH: MM hospital admission (result in minutes)
This indicator reports on DTN times only in the subgroup of patients undergoing bridging therapy (IVT + EVT). Thus, it is not optimal for assessing quality of stroke care process by hospital level since it is not including the whole sample of IVT patients.
Metric 5: 75% of patients who underwent bridging treatment should have a door to needle time < or = 40 minutes. In those Centers with a large volume of patients and with a well-established infrastructure, the time should be less than 30 minutes.

Indicator 6: Puncture time to reperfusion
Definition: time from the arterial puncture that initiates the EVT to the achievement of a successful revascularization defined as the time in which a mTICI> = 2b is reached for the first time
Calculation: ddmmyyyy/HH: MM mTICI> = 2b - ddmmyyyy/HH: MM arterial puncture (result in minutes)
Metric 6: 70% of EVT patients reach an mTICI >= 2b in the first 60 minutes.

Indicator 7: % of patients who undergo an imaging test after EVT
Definition: percentage of patients who undergo an imaging test in the 36 hours after the completion of EVT
Calculation: (number of patients who undergo an imaging test within 36 hours after the completion of the EVT / number of patients receiving EVT) * 100

Metric 7: 100% of alive patients should have a follow-up neuroimaging < = 36 hours after EVT.

Indicator 8: % of SICH
Definition: percentage of patients with SICH (as per the SITS MOST definition) after EVT.
Calculation: (number of patients with SICH after EVT / number of patients receiving EVT) * 100
Metric 8: less than 10% of patients receiving EVT should develop a SICH

Indicator 9: % of patients with embolizations in new territories
Definition: percentage of patients presenting embolizations in territories not initially affected as a result of thrombus fragmentation during EVT
Calculation: (number of patients presenting with embolizations in territories not affected initially as a result of thrombus fragmentation during EVT / number of patients receiving EVT) * 100
Metric 9: less than 10% of patients should have an embolization in a new territory

4.2. Outcomes indicators/metrics

Indicator 10: % of patients treated with EVT in the region or rate of EVT in the region per 100,000 inhabitants -year
Definition: percentage of patients treated with EVT in the region OR regional population-based EVT rate
Calculation: (number of patients treated with EVT / number of AIS in the region) * 100 OR (Number of patients treated with EVT / number of inhabitants in the region) * 100,000 inhabitants-year
Results will be presented as crude and standardize rates.
Metric 10: (Aguiar de Souza D, et al. European Stroke Journal 2018:x:1–16)
% of EVT among AIS population: 5-7%
Population-based EVT rate: 8 * 100,000

Indicator 11: % of patients achieving successful revascularization
Definition: percentage of patients receiving EVT that achieve a >=2b mTICI score immediately after removal of the thrombus that produces the occlusion of the affected vessel.
Calculation: (number of patients receiving EVT that achieve a >=2b mTICI score after removal of the thrombus that produces occlusion of the affected vessel / number of patients receiving EVT) * 100
Metric 11: at least 70% of patients must have a >=2b mTICI score at the end of the EVT (for all anterior circulation locations).

Indicator 12: % of patients with mRS assessed at 90 days

Definition: percentage of EVT patients who have their functional status assessed at 90 days by the mRS
Calculation: (number of EVT patients with a mRS evaluated at 90 days / number of patients receiving EVT) * 100
Metric 12: at least 90% of patients who have received EVT should have documented the mRS at 90 days.

Indicator 13: % of independent patients 90 days after receiving EVT
Definition: percentage of patients with a mRS 0-2 score 90 days after the EVT.
Calculation: (number of patients with a mRS score 0-2 at 90 days of the endovascular procedure / number of patients receiving EVT) * 100
Metric 13: of all treated patients, at least 30% are independent at 90 days. Includes posterior circulation strokes as well as patients with premorbid mRS = > 3.

5. LIST OF VARIABLES

	Name of the variable	Type (final decision)
1	**Id region**	minimum set
2	**Id patient/event**	minimum set
3	**Resident in the area**	minimum set
4	**Sex**	minimum set
5	**Age**	minimum set
6	**Previous mRS**	minimum set
7	**High blood pressure/Hypertension**	minimum set
8	**Diabetes mellitus**	minimum set
9	**Dyslipidemia**	minimum set
10	**Smoking**	minimum set
11	**Previous stroke/TIA**	minimum set
12	**Previous AMI**	minimum set
13	**Atrial fibrillation**	minimum set
14	**Anticoagulation**	minimum set
15	**INR**	minimum set
16	**Unknown onset time**	minimum set
17	**Date/time of symptoms onset (or last time seen asymptomatic)**	minimum set
18	**Date/time of arrival at 1st hospital**	minimum set
19	**Diagnostic**	minimum set
20	**Date/ time of 1st imaging**	minimum set
21	**Type of imaging**	minimum set
22	**Type of vascular imaging**	minimum set
23	**ASPECTS score in 1st imaging**	minimum set
24	**Initial NIHSS**	minimum set
25	**Large vessel occlusion**	minimum set
26	**Vessel affected**	minimum set

27	**Reperfusion treatment administered**	minimum set
28	**Date/ time of iv thrombolysis**	minimum set
29	**Type of thrombolityc treatment**	Recommendable
30	**Transfer from another hospital for EVT**	minimum set
31	**Date/ time of arrival at CSC**	minimum set
32	**Date/ time of 2nd imaging**	Recommendable
33	**ASPECTS score pre arteriography**	minimum set
34	**NIHSS pre arteriography**	minimum set
35	**Date/ time of arterial puncture**	minimum set
36	**EVT modality**	Recommendable
37	**Occlusion by arteriography**	minimum set
38	**Initial mTICI score**	minimum set
39	**Device model**	Recommendable
40	**Number of passes**	Recommendable
41	**Use of balloon**	Recommendable
42	**Stent**	Recommendable
43	**Final mTICI score**	minimum set
44	**Date/ time of revascularization/ end of procedure**	minimum set
45	**Embolization to new territories?**	minimum set
46	**Neuroimaging <= 36 h post-EVT**	minimum set
47	**SICH (SITS-MOST definition)**	minimum set
48	**3 month mRS**	minimum set
49	**3 month mRS score**	minimum set
50	**Death date**	Recommendable
51	**admission systolic/diastolic blood pressure**	recommendable
52	**admission blood glucose**	recommendable
53	**prior antiplatelet therapy**	recommendable
54	**type of antiplatelet therapy**	recommendable

Note: Those variables added in the last version are marked in orange

6. Annexes

6.1. Table 1. mTICI score (3-5)

Score	Description
0	No perfusion, complete obstruction; there is no flow after occlusion of a large vessel
1	Perfusion after initial occlusion, but limited to filling of distal branches with sparse or slow distal perfusion
2a	Partial perfusion: <50% of the vascular territory of the occluded artery (eg, filling and complete perfusion through a branch of the M2 division)
2b	Partial perfusion:> = 50% of the vascular territory of the occluded artery, but there is no complete and normal perfusion of the entire territory
2c	Nearly complete perfusion, except for slow flow in some distal cortical vessels or presence of small distal cortical emboli
3	Complete perfusion with filling of all distal branches

6.2. Table 2. Modified Rankin scale

Score	Description
0	Asymptomatic
1	Non-significant disability: able to carry out all usual activities despite the symptoms
2	Mild disability: able to fend for himself without assistance, but unable to carry out all the activities he previously could do normally
3	Moderate disability: requires some help, but is able to walk without assistance.
4	Moderately severe disability: unable to meet the needs of your body without assistance, and unable to walk without assistance.
5	Serious disability: requires constant care and attention of nurses, prostrate, incontinent
6	Death

6.3. Tabla 3. Metrics

Number	Description
1	% of patients with the required data entered in the registry
2	Symptoms to door
3	Door to puncture
4	Imaging to puncture
5	Door to needle time
6	Puncture time to reperfusion

7	% of patients who undergo an imaging test after EVT
8	% of SICH
9	% embolizations in new territories
10	% of AIS patients treated with EVT OR population EVT rate
11	% of patients who achieve successful revascularization
12	% of patients with mRS at 90 days
13	% of independent patients within 90 days of receiving EVT

7. REFERENCES

(1) Sacks, David et al.Multisociety Consensus Quality Improvement Revised Consensus Statement for Endovascular Therapy of Acute Ischemic Stroke. Journal of Vascular and Interventional Radiology , 2018, Volume 29 , Issue 4 , 441 – 453

(2) Sacco RL, et al; American Heart Association Stroke Council, Council on Cardiovascular Surgery and Anesthesia; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular and Stroke Nursing; Council on Epidemiology and Prevention; Council on Peripheral Vascular Disease; Council on Nutrition, Physical Activity and Metabolism. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013 Jul;44(7):2064-89. doi: 10.1161/STR.0b013e318296aeca.

(3) Dargazanli C et al. Modified Thrombolysis in Cerebral Infarction 2C/Thrombolysis in Cerebral Infarction 3 Reperfusion Should Be the Aim of Mechanical Thrombectomy Stroke. 2018;49:1189-1196

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