Stroke Toolkit Guideline v2.0

Instruments

Toolkit Purpose

A collection of measures to capture essential phenotypes associated with Stroke-related biomedical research.

Guideline Description

The Stroke toolkit can be used to collect essential phenotypes associated with Stroke-related research, including: Stroke Characterisation; Stroke Verification; Primary Prevention and Secondary Prevention. The following document establishes guidelines (particularly applicable in Africa) on how to use the toolkit and collect detailed, relevant and harmonized phenotype and exposure data for research.

As listed below, the Stroke toolkit consists of 3 Instruments, labelled **Instruments 1 to 3:**

Instrument	**Phenotypes**
1	Stroke Characterisation
2	Pre-Stroke Risk Reduction Strategies
3	Post-Stroke Risk Reduction Strategies

Important Notes

1. The toolkit employs branching logic, therefore, we recommend that it is completed in order, as some variables may or may not appear OR accept input based on the input of previously listed variables.

2. Some branching logic (specifically related to date of birth/age and biological sex) affect the display of items relevant to adult or paediatric participants across multiple instruments.

3. Any addition or removal of variables may also affect branching logic so editing of variables should be carefully positioned so as not to interrupt branching logic conditions with related variables.

4. The toolkit is recommended to be used in conjunction with the Core Phenotypes toolkit (https://github.com/h3abionet/h3aphenstds).

5. Although not highlighted below, each instrument requires a collection date, which can be collected either manually or automatically.

6. Consistent codes are recommended for the identification of missing data, and these are incorporated into all Instruments discussed below.

7. Codes for Missing Data are specified below:

Code	Value Label
-991	No information
-992	Asked but unknown
-993	Temporarily unavailable
-994	Not asked
-995	Refused
-998	Not applicable

8. We recommend that when a participant responds with an "I don't know" to a question that the interviewer firstly ensures that the participant understands the question clearly and secondly is gently encouraged to reconsider their response if possible. If "I don't know" is still the response we make use of the 'Asked but unknown' missing code. Questions where "I don't know" is a highly anticipated and valid response will have a checkbox for Unknown included - it should be noted that this will not be recognised as missing data in statistical software.

Recommendations

Instrument 1: Stroke Characterisation

The instrument enables the collection of information related to the stroke status and characterisation of research participants, as well as the verification thereof.

Questions	Is the participant currently a stroke patient? **Response Options**: Yes; No (If Yes) Which side of the body is affected? **Response Options**: Right; Left; Both (If Yes) What was the participant's disability status after the most recent stroke? **Response Options**: No symptoms; No significant disability; Slight disability; Moderate disability;

	Moderately severe disability; Severe disability How was the stroke verified? **Response Options**: CT; MRI; Angiography; Not Verified When was the first scan taken after onset of stroke symptoms: **Response Options**: Within 24hrs; 24 - 48hrs; 48 - 72hrs; 72hrs - 1wk; 1wk - 2wks; After 2wks Was the most recent stroke episode a transient ischemic attack? **Response Options**: Yes; No; Not Assessed Facial weakness detected/observed: **Response Options**: Yes; No; Not Assessed
Notes	- **Stroke** - Sudden impairment of blood flow to a part of the brain due to occlusion or rupture of an artery to the brain. - **Transient Ischemic Attack (TIA)** - A brief attack (from a few minutes to an hour) of cerebral dysfunction of vascular origin, with no persistent neurological deficit. - **Disability severities** defined… - **No significant disability** - Able to carry out all usual activities, despite some stroke symptoms. - **Slight disability** - Able to look after own affairs without assistance, but unable to carry out all previous activities. - **Moderate disability** - Requires some help, but able to walk unassisted. - **Moderately severe disability -** Unable to attend to own bodily needs without assistance, and unable to walk unassisted. - **Severe disability** - Requires constant nursing care and attention, bedridden, incontinent.
Questions	Stroke Type: **Response Options**: Ischemic; Hemorrhagic; Ischemic with Hemorrhagic transformation; Both discrete ischemic and hemorrhagic transformation" Location of Lesion: (If Ischemic) OSCP Classification **Response Options**: TACI; PACI; POCI; LACI [(If Ischemic) ASCOD Classification Atherosclerosis Small Vessel Disease Cardioembolism Other causes Dissection] **Response Options**: 0; 1; 2; 3; 9
Notes	- **Ischemic**: A stroke which happens when blood flow through the artery that supplies oxygen-rich blood to the brain becomes blocked. - **Hemorrhagic**: A stroke which happens when an artery in the brain leaks blood or ruptures (breaks open). The leaked blood puts too much pressure on brain cells, which damages them. - **OSCP Classification:** - TACI: total anterior circulation infarct

	- PACI: partial anterior circulation infarct - POCI: posterior circulation infarcts - LACI: lacunar infarct - **ASCOD Classification**: grade the severity of EACH cause below (each of the 5 phenotypes can be graded 1, 2, or 3) - **Arteriolosclerosis** - Disease characterized by thickening of the wall of the small arteries and arterioles, caused by deposition of hyaline material in the wall or concentric smooth muscle wall hypertrophy, and results in lumen narrowing and tissue ischemia. - **Small Vessel Disease** - Pathological processes that affect the brain parenchymal circulation (arterioles, capillaries, and veins). It is a major contributor to stroke, and a leading cause of cognitive impairment and dementia. - **Cardioembolism** - An embolism that is a result of an obstruction in a cardiac vessel due to a blood clot or other foreign matters - **Dissection** - The process of cutting apart or separating tissue as, for example, in the study of anatomy or in the course of a surgical procedure. - **Other Cause** - Other causes not including the aforementioned four.

Instrument 2: Pre-Stroke Risk Reduction Strategies

This instrument enables the collection of self-reported information related to the employment of strategies to prevent stroke occurrence in individuals who have not previously experienced a stroke.

Questions	Has the participant ever employed risk reduction strategies to prevent stroke? **Response Options**: Yes; No (If Yes) Specify stroke risk reduction strategies employed: **Response Options**: Antiarrhythmics; Anticoagulant therapy; Antidiabetics; Antihypertensive drug therapy; Antilipids; Antiplatelet therapy; Smoking Cessation; Dietary changes; Physical Activity changes; Statin therapy; Surgical Procedure; Other (If Other) Specify other stroke risk reduction strategies employed:
Notes	- **Antiarrhythmics** - Medication used to treat abnormal heart rhythms resulting from irregular electrical activity of the heart. - **Anticoagulants** - Medication capable of preventing blood clot formation. - **Antidiabetics** - Medication that works to lower abnormally high glucose (sugar) levels in the blood. - **Antihypertensives** - Medication used in the treatment of acute or chronic hypertension regardless of pharmacological mechanism.

	- **Antilipids** - Lipid-lowering agents, also sometimes referred to as hypolipidemic agents, cholesterol-lowering drugs, or antihyperlipidemic agents are a diverse group of pharmaceuticals that are used to lower the level of lipids and lipoproteins such as cholesterol, in the blood. - **Antiplatelets** - Medicines that stop cells in the blood (platelets) from sticking together and forming a clot. - **Statins** - A class of medication used to lower cholesterol. - **Smoking Cessation** - Discontinuation of the habit of smoking.

Instrument 3: Post-Stroke Risk Reduction Strategies

This instrument enables the collection of self-reported information related to the employment of strategies to prevent stroke occurrence in individuals who have previously experienced a stroke.

Questions	Has the participant ever employed any post-stroke risk reduction strategies? **Response Options**: Yes; No (If Yes) Specify post-stroke risk reduction strategies employed: **Response Options**: Antiarrhythmics; Anticoagulant therapy; Antidiabetics; Antihypertensive drug therapy; Antilipids; Antiplatelet therapy; Smoking Cessation; Dietary changes; Physical Activity changes; Statin therapy; Surgical Procedure; Other (If Other) Specify other post-stroke risk reduction strategies employed:
Notes	- **See Instrument 2 Notes** for further explanation on risk-reduction strategies included.

Abbreviations

ASCOD: Atherosclerosis, Small vessel disease, Cardiac source, Other cause, Dissection
CT scan: Computerized Tomography scan
LACI: Lacunar Infarct
MRI: Magnetic Resonance Imaging
OSCP: Oxfordshire Community Stroke Project
PACI: Partial Anterior Circulation Infarct
POCI: Posterior Circulation infarct
TACI: Total Anterior Circulation Infarct

TIA: Transient Ischemic Attack

Administration

Mode of Administration

	Instruments		
	1	2	3
Interview OR Self-administered questionnaire	X	X	X
Clinical assessment	X		
Bioassay/Lab- based assessment			

Life Stage

	Instruments		
	1	2	3
Infancy (0 - 12 months)			
Toddler (13 - 24 months)			
Childhood (2-11 years)			
Adolescence (12 - 18 years)			
Adult (18 and older)	X	X	X

Personnel and Training Required

Instruments 1 needs to be conducted by or the information needs to be retrieved from the records of qualified and experienced healthcare personnel.Information may also be recorded from hospital and(or) patient records. **Instrument 2 and 3** may be implemented as either self-reported questionnaires or interviewer- administered questionnaires. If interviewer- administered, interviews should be conducted by trained or study coordinators or data collectors who speak the native/local language of the target population.

References

The Stroke toolkit is based on and aligned with several existing standards, to facilitate data harmonisation. These resources are listed below:

1. H3Africa SIREN Case Report Forms (CRFs)

Contributors

Phenotype Harmonisation WG - H3Africa
Joint Phenotype Harmonisation Project - H3ABioNet
Phenotype Standardisation Project - H3ABioNet
Faniyan Moyinoluwalogo
Judit Kumuthini
Lyndon Zass
Mayowa Owolabi
Melek Chaouch
Michael Thompson
Paul Olowoyo

Contact Us

For queries related to this standard and guideline, users can log a ticket to the Phenotypes Standards queue in the H3ABioNet Helpdesk. User feedback and improvements on the current toolkit are welcome and encouraged. These can also be submitted through the Helpdesk, or on our GitHub Issues page.