# Data Elements and Definitions for a Case Registry Study of Acupuncture for Stroke: Postprint

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## Abstract

The prevention and treatment of stroke has consistently been a focal point of attention in the global medical community, with the unique advantages of acupuncture therapy for stroke becoming increasingly prominent. The *Chinese Guidelines for Acute Ischemic Stroke 2018* recommends acupuncture treatment for patients with acute cerebral infarction (Level II recommendation, Grade B evidence). Standardized and normalized clinical research data can ensure data quality and provide a foundation for data curation and mining. Case registration constitutes a form of real-world research, and consistency of data elements is an essential prerequisite for ensuring effective protocol implementation, high data quality, and credible clinical research evidence. Therefore, based on the key research and development program project "Case Registration Study of Acupuncture Treatment for Stroke," our research team has formulated the data elements and definitions for this study, aiming to optimize the clinical research paradigm for acupuncture in the prevention and treatment of stroke.

## Full Text

### Case Registry Study of Acupuncture Treatment for Stroke Disease: Data Elements and Definitions

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**Abstract**

Stroke prevention and treatment has long been a focal point for the global medical community, with the unique advantages of acupuncture for stroke management becoming increasingly prominent. The *Chinese Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke 2018* recommends acupuncture therapy for patients with acute cerebral infarction (Grade II recommendation, Level B evidence). Standardized and normalized clinical research data is essential to ensure data quality and facilitate data processing and mining. Case registry studies constitute a form of real-world research, and consistency in data elements is a critical prerequisite for ensuring protocol implementation, efficient data quality, and credible clinical research evidence. Therefore, based on the national key research and development project "Case Registry Study of Acupuncture Treatment for Stroke Disease" (Project No.: 2019YFC0840709), our research group has developed data elements and definitions for this project to optimize the clinical research paradigm for acupuncture in stroke prevention and treatment.

**Keywords:** Acupuncture; Registration; Data elements; Data quality; Research paradigm

## Introduction

The prevalence of unhealthy lifestyles among residents has led to a widespread increase in stroke risk factors, imposing a heavy economic burden on both the nation and society. Numerous studies have demonstrated that acupuncture yields definitive therapeutic effects in improving stroke symptoms, reducing neurological deficits, and enhancing patients' quality of life. However, due to the independence of research data across institutions and the lack of standardized data structures, variable definitions and domain values have varied considerably between institutions and even among studies on the same disease, lacking uniformity. This has severely limited data sharing and integration, restricting further mining of valuable data and the broad application of big data technology in acupuncture treatment for stroke disease [1].

Real-world studies (RWS) can reflect actual clinical practice regarding patient health status and medical service processes, with research results demonstrating good external validity that complements randomized controlled trials in providing clinical evidence for acupuncture therapy in stroke treatment. Case registry studies (CRS), as a type of RWS, are still in their infancy in the acupuncture field. During the planning phase, identifying registry data elements and establishing clear data definitions facilitates clinical data entry and collection,

enabling standardized and normalized data acquisition throughout the research process while reducing the burden of data collection and extraction training.

The Agency for Healthcare Research and Quality (AHRQ) published the *Registries for Evaluating Patient Outcomes: A User' s Guide (2nd Edition)* in 2010, which provides clear definitions and explanations for all aspects of registry research from design and implementation to evaluation, offering reliable safeguards for standardized registry research. Data elements are data standards formulated according to research objectives and scientific questions to be addressed, primarily comprising data elements and data definitions. Data elements and definitions are crucial for ensuring internal consistency in planned research, enabling reproducible data acquisition pathways and uniform domain values among personnel. Data definitions involve the rationale for each data element and its domain values, as well as indicating possible logical relationships between different data elements. According to research objectives and content, not every data element is essential; therefore, determining which data elements are indispensable and which are irrelevant is critical in the registration process. Data element selection should follow principles of simplicity, accuracy, and consistency to achieve research objectives. The steps for determining data elements include: (1) Defining registry scope: establishing research objectives; identifying the scope of information that may affect research outcomes; requiring integration of currently recognized clinical data standards and definitions for specific data elements, or supplementing with individually collected information when recognized standards are lacking; (2) Selecting data elements: identifying data elements that best fit the defined scope and data sources, determining data classification, evaluation, and statistical methods to achieve research objectives, with reference to existing data standards in the research field; (3) Mapping registry data: creating data tables containing all data elements, data sources, and data definitions; (4) Pilot testing: conducting pilot tests using data collection tools (case report forms, data management platforms, etc.) to determine the time and workload required for form completion, further revising registry forms to finalize comprehensive data elements and definitions [2].

The research group for the national key R&D project "Case Registry Study of Acupuncture Treatment for Stroke Disease" (No. 2019YFC0840709), 依托 the National Clinical Research Center for Chinese Medicine Acupuncture and Moxibustion clinical research network system, comprises teams of clinical acupuncture experts, epidemiologists, statistical analysts, and platform database professionals, including acupuncture discipline leaders from over 30 tertiary hospitals nationwide. To develop standardized data elements and clarify their definitions, the research group established data elements for the acupuncture stroke registry study based on research objectives, referencing the *China National Stroke Database* and the *Expert Consensus on Core Data Elements and Definitions for Stroke Clinical Diagnosis and Disease Management 2020*. Drawing upon the *Diagnostic and Efficacy Evaluation Criteria for Stroke Disease (Trial 1995)*, the *National Administration of Traditional Chinese Medicine Clinical Terminology 2020*, the *China Cerebrovascular Disease Classification 2015*, and the *Chinese*

*Guidelines for Integrated Traditional Chinese and Western Medicine Diagnosis and Treatment of Cerebral Infarction 2017*, the group formulated the "Data Elements and Definitions for the Case Registry Study of Acupuncture Treatment for Stroke Disease" . According to the classification standards for registry information in AHRQ' s *Registries for Evaluating Patient Outcomes: A User' s Guide (2nd Edition)*, data elements primarily include personal information, exposure information, and evaluation/outcome information for stroke patients. These data elements are primarily used for clinical diagnosis and treatment, disease management, and research data collection during hospitalization and follow-up periods for studies focusing on acupuncture treatment for stroke disease, and can also serve as a reference for developing clinical research data variables for stroke disease and its sequelae.

Under the premise of ensuring data security, this study registers clinical diagnosis and treatment information and follow-up data for acupuncture in stroke prevention and treatment, achieving full-process management of clinical data collection, processing, and storage. Fully integrating characteristics of traditional Chinese medicine (TCM) acupuncture, the study collects and organizes TCM four diagnostic information and acupuncture dose-effect parameters to establish a case registry database for acupuncture in stroke prevention and treatment. This will analyze real-world application characteristics and action patterns of acupuncture for stroke disease, explore key clinical application elements, optimize acupuncture prevention and treatment protocols for stroke disease, improve clinical service quality, and optimize the clinical research paradigm for acupuncture in stroke prevention and treatment.

## 1. Personal Information Data Elements for Stroke Patients

Personal information includes data describing patients, comprising demographic data, disease history, and past health status.

### 1.1 Demographic Information Data Elements and Definitions

Demographic information data elements include general patient information, medical insurance category, medical institution name, contact phone number, WeChat ID, native place, long-term residence location, education level, and basic occupational information, totaling 14 elements (Table 1). All data element definitions adopt those issued by national health industry standards, referencing the *Expert Consensus on Core Data Elements and Definitions for Stroke Clinical Diagnosis and Disease Management* [1] and the *Basic Medical Record Writing Standards* issued by the Ministry of Health in 2002. This project added data elements for native place, long-term residence, education level, and occupation, as studies have confirmed that stroke incidence rates in some northwestern, northern, and northeastern provinces reach as high as 236 per 100,000 population, significantly higher than the 110 per 100,000 in other provinces. Registering stroke patients' birthplace and long-term residence facilitates statistical analysis of regional differences in stroke incidence. Education level is well-known

to be closely related to cognitive dysfunction after stroke, representing a major factor affecting post-stroke cognitive impairment and cognitive function in the elderly. Occupation and medical insurance category may influence patients' time to seek medical care after onset, directly affecting disease prognosis.

**Table 1 Demographic Information Data Elements and Definitions**

*Data Element Name and Definition:* Name, gender, ethnicity, date of birth, ID number, marital status, medical insurance category, medical institution name, contact phone number, WeChat ID: Refer to the *Expert Consensus on Core Data Elements and Definitions for Stroke Clinical Diagnosis and Disease Management*.

*Native Place:* The long-term residence or birthplace of an individual' s paternal ancestors (grandfather level and above). Format: Province (autonomous region, municipality) - City (prefecture, autonomous prefecture) - County (district).

*Long-term Residence Location:* An individual' s residence for more than one year. Format: Province (autonomous region, municipality) - City (prefecture, autonomous prefecture) - County (district).

*Education Level:* The academic degree (requiring a nationally recognized diploma) or degree (requiring corresponding certificate) obtained by an individual. According to national education level coding standards, categories include: postgraduate, undergraduate, junior college and specialized colleges, secondary specialized or technical schools, technical worker schools, high school, junior high school, primary school, illiterate or semi-illiterate.

*Occupation:* Work that serves society and provides the main source of livelihood. Referencing the *Occupational Classification Dictionary of the People' s Republic of China (2015 Edition)*, occupational categories include: civil servant, professional and technical personnel, staff, enterprise management personnel, worker, farmer, student, active-duty military personnel, freelancer, self-employed, unemployed, retired, and other.

### 1.2 Disease History Information Data Elements and Definitions

Disease history information data elements total 14 items (Table 2 ), including patients' past medical history of hypertension, hyperlipidemia, hyperglycemia, coronary heart disease, personal lifestyle habits (smoking, alcohol consumption, dietary preferences, temperament), and past physical condition. These factors significantly influence stroke incidence, severity, and prognosis. The *Huangdi Neijing* describes human emotions and dietary regimens, stating that "a tranquil mind with few desires and a peaceful heart without fear" reflects the close relationship between emotional injury and disease. Additionally, diet is the primary source of nutrients for maintaining health, emphasizing dietary diversity while strongly opposing 偏食 (dietary bias) and 偏嗜五味 (partiality for the five flavors). All other data element definitions adopt those issued by national health industry standards or diagnostic criteria.

**Table 2 Data Elements and Definitions of Disease History Information**

*Common Disease History:* Diagnostic criteria for hypertension, dyslipidemia, and diabetes refer to the *Expert Consensus on Core Data Elements and Definitions for Stroke Clinical Diagnosis and Disease Management* [1].

*Hyperhomocysteinemia:* Identifies whether the patient had diagnosed hyperhomocysteinemia or was taking related medications before this onset. Diagnostic criteria follow the *Expert Consensus on Diagnosis and Treatment of Hyperhomocysteinemia (2020)* [3] issued by the Bone Health and Nutrition Professional Committee of the Chinese Nutrition Society, Chinese Society for Parenteral and Enteral Nutrition, and Northern Chronic Disease Prevention and Treatment Branch of the Chinese Geriatrics Society. Includes: Various factors can cause accumulation of total homocysteine (tHcy) levels, forming hyperhomocysteinemia (HHcy), abbreviated as high blood homocysteine. Adult blood homocysteine $ $10 mol/L is diagnosed as hyperhomocysteinemia, classified as mild (10-15 mol/L), moderate (15-30 mol/L), or severe (>30 mol/L).

*Coronary Atherosclerotic Heart Disease:* Identifies whether the patient had diagnosed coronary heart disease or was taking medications before this onset. Diagnostic criteria follow the *Guidelines for Traditional Chinese Medicine Diagnosis and Treatment of Stable Angina Pectoris in Coronary Heart Disease (2019)* [4]. Includes: Diagnosis is based on typical attack characteristics and signs (paroxysmal anterior chest compressive pain or suffocation sensation, mainly located behind the sternum, radiating to the precordial area and left upper limb ulnar side, often occurring with increased workload, lasting several minutes), relieved by rest or nitroglycerin, combined with age and existing coronary risk factors, excluding angina caused by other diseases. Auxiliary examinations must meet: (1) reduced coronary blood flow; (2) myocardial ischemia, hypoxia, or necrosis causing heart disease. Coronary angiography and CT coronary 3D reconstruction are commonly used to detect coronary stenosis or dilation degree to determine blood flow reduction. Clinical identification of myocardial ischemia, hypoxia, and necrosis is primarily based on angina symptoms, ECG manifestations of myocardial ischemia or necrosis, radionuclide myocardial imaging, and ultrasound detection of cardiac motion abnormalities caused by myocardial ischemia and necrosis.

*Atrial Fibrillation:* Identifies whether the patient had diagnosed atrial fibrillation before this onset. Diagnostic criteria follow the *2020 ESC Guidelines for the Diagnosis and Management of Atrial Fibrillation* [5]. Includes: A standard 12-lead ECG or $ $30s single-lead ECG showing no obvious repetitive P waves and irregular RR intervals (without impairing atrioventricular conduction) can confirm diagnosis.

*Myocardial Infarction:* Identifies whether the patient had diagnosed myocardial infarction before this onset. Diagnostic criteria follow the *Guidelines for Primary Diagnosis and Treatment of ST-Segment Elevation Myocardial Infarction (2019)* [6]. Myocardial infarction diagnosis (meeting one of the following

conditions): Detection of elevated or decreased cardiac biomarkers (primarily cTn) with at least one value exceeding the 99th percentile of the upper limit of normal, and at least one of the following: myocardial ischemia symptoms; new or suspected new significant ST-T changes on ECG or new left bundle branch block; pathological Q waves on ECG; imaging evidence of new loss of viable myocardium or new regional wall motion abnormalities; angiographic or autopsy evidence of coronary thrombosis.

*Sleep Apnea Syndrome:* Identifies whether the patient had diagnosed sleep apnea before this onset. Diagnosis is based on polysomnography (PSG) monitoring results, the gold standard for diagnosing sleep apnea syndrome (Obstructive Sleep Apnea-Hypopnea Syndrome, OSAHS) [7,8]. Includes: Apnea refers to cessation of oral and nasal airflow for at least 10 seconds; hypopnea refers to respiratory airflow reduction to 20-50% of normal intensity accompanied by 4% oxygen saturation decrease. When the above conditions coexist with thoracoabdominal respiratory movement, it is considered obstructive sleep apnea or hypopnea. During 7 hours of nighttime sleep, recurrent obstructive sleep apnea and hypopnea occurring more than 30 times or more than 5 times per hour of sleep can confirm diagnosis.

*Other Past Medical History:* Refers to the patient' s past health and disease conditions, identifying previous general health status, surgical and trauma history, transfusion history, food or drug allergy history, etc.

*Smoking and Alcohol Consumption:* Definitions refer to the *Expert Consensus on Core Data Elements and Definitions for Stroke Clinical Diagnosis and Disease Management* [1].

*Dietary Preferences:* Description of the patient' s current or past dietary situation. Referencing *Fundamentals of Traditional Chinese Medicine*, record whether there is dietary bias and the specific bias, including: type bias (grains, meat, fruits, vegetables), temperature bias (raw/cold/cool, pungent/warm/dry-heat), five-flavor bias (sour, bitter, sweet, pungent, salty). Categories include: light, rich and greasy, spicy stimulation, no bias, other.

*Temperament:* Description of the patient' s temperament. Referencing *Fundamentals of Traditional Chinese Medicine*, including: balanced, irritable and easily angered, low mood, other.

*Family History:* Referencing *Fundamentals of Traditional Chinese Medicine*, including: whether parents, siblings have hypertension, diabetes, coronary heart disease, stroke (cerebral infarction or cerebral hemorrhage).

## 2. Exposure Information Data Elements for Stroke Patients

Exposure information data elements include clinical symptoms, signs, and treatment process information for stroke patients.

### 2.1 Clinical Symptoms, Signs, Diagnosis, and Complications Data Elements and Definitions

Clinical symptoms, signs, diagnosis, and complications data elements total 20 items (Table 3 ), primarily incorporating stroke-related data elements. Whether stroke patients receive thrombolysis or thrombectomy during the acute phase is closely related to onset time and time to treatment. The Oxfordshire Community Stroke Project (OCSP) stroke classification is a key factor influencing secondary prevention treatment decisions. Stroke syndrome elements exhibit periodicity and regularity related to solar terms. Body Mass Index (BMI) is calculated from height and weight data elements, sourced from national health industry standards. This project aims to explore the action patterns of TCM acupuncture in stroke prevention and treatment, with the registration process fully reflecting TCM characteristics, including TCM symptoms, syndromes, and signs. TCM syndrome references the *Diagnostic and Efficacy Evaluation Criteria for Stroke Disease (Trial 1995)* drafted by the National Administration of Traditional Chinese Medicine Emergency Brain Disease Research Collaboration Group and the *TCM Clinical Terminology - Syndromes* issued by the National Administration of Traditional Chinese Medicine and National Health Commission. Research data shows that 50-67% of stroke patients have concomitant swallowing disorders, which can easily lead to aspiration and approximately 40% develop aspiration pneumonia [9], with a 30-day mortality rate of 21-30% [10]. Patients with swallowing disorders using gastric tubes often develop electrolyte disturbances and nutritional disorders, further increasing the risk of poor prognosis. Therefore, early screening and assessment of swallowing disorders, along with effective interventions, help promote swallowing function recovery, reduce more severe complications, and improve outcomes for stroke patients [11]. Common complications during hospitalization for cerebrovascular disease patients include post-infarct hemorrhagic transformation, stroke-associated pneumonia, deep vein thrombosis, pulmonary embolism, cerebral edema, and increased intracranial pressure, while epilepsy, urinary tract infection, post-stroke constipation, post-stroke urinary dysfunction, pressure ulcers, and malnutrition are also common and often clinically overlooked. Most of these 11 complications significantly impact patient prognosis, and timely effective intervention can improve quality of life and survival rates. Definitions for complication information and other data elements adopt those issued in national health industry standards such as *Neurology* (8th Edition).

**Table 3 Data Elements and Definitions of Clinical Symptoms and Signs, Diagnosis and Complications**

*Solar Term at Onset:* Identifies the solar term when the patient developed symptoms. There are 24 solar terms throughout the year.

*Specific Onset Time:* The exact time (year, month, day, hour) of the patient' s current stroke onset.

*Admission Time:* The exact time (year, month, day, hour) when the patient

completed admission procedures at the first medical institution after onset.

*Body Mass Index (BMI):* Calculated as: BMI = weight (kg) / [height (m)]$^2$.

*Vital Signs:* Identifies temperature, heart rate, respiration, and blood pressure at admission.

*Chief Complaint:* Includes main symptoms, onset time, and disease progression or evolution.

*TCM Clinical Symptoms:* TCM syndrome references the *Diagnostic and Efficacy Evaluation Criteria for Stroke Disease (Trial 1995)* [12] and the *TCM Clinical Terminology - Syndromes* [13] issued by the National Administration of Traditional Chinese Medicine and National Health Commission. Mainly includes: hemiplegia (flaccid/spastic), impaired consciousness, slurred speech or aphasia, hemisensory abnormalities, deviated tongue and mouth, headache, dizziness, pupil changes, choking when drinking water, eye deviation without blinking, ataxia, sleep disorders, limb numbness, bowel and bladder dysfunction or incontinence, and others.

*Tongue Appearance:* Observation of tongue quality and coating morphology, color, moisture, etc., through tongue diagnosis.

*Pulse Condition:* Pulse obtained through palpation.

*Neurological Examination:* Neurological examination refers to *Neurology* (8th Edition). Pharyngeal reflex: Using a tongue depressor to gently touch the posterior pharyngeal wall, normally eliciting a gag reflex (pharyngeal muscle contraction) as a physiological reflex. Motor function examination: includes muscle strength, muscle tone, and involuntary movement assessment. Coordination examination: includes finger-to-nose test, alternating movements test, heel-knee-shin test, and Romberg test. Sensory function examination: includes superficial, deep, and composite sensation assessment. Pathological signs: includes palmomental reflex, Hoffmann' s sign, Babinski sign, Chaddock sign, Oppenheim sign, Gordon sign, neck stiffness, Kernig sign, and Brudzinski sign assessment.

*TCM Syndrome Differentiation:* Identifies TCM pattern types, referencing the *Chinese Guidelines for Integrated Traditional Chinese and Western Medicine Diagnosis and Treatment of Cerebral Infarction (2017)* [14], including: Meridian stroke: wind-phlegm obstructing collaterals pattern, wind-fire disturbing upward pattern, qi deficiency and blood stasis pattern, yin deficiency with wind movement pattern, liver-kidney deficiency pattern; Visceral stroke: phlegm-dampness clouding spirit pattern, phlegm-heat internal closure pattern, original qi collapse pattern.

*Cerebral Infarction and Location:* (1) Diagnostic criteria: Refer to the *China Diagnostic Points for Major Cerebrovascular Diseases 2019* [15] formulated by the Neurology Branch and Cerebrovascular Disease Group of the Chinese Medical

Association, meeting diagnostic points for cerebral infarction. (2) Cerebral infarction location: Refer to the "12th Five-Year"national undergraduate planning textbook *Neurology (7th Edition)*: locations include frontal lobe, parietal lobe, temporal lobe, occipital lobe, insular lobe, centrum semiovale, basal ganglia, hypothalamus, brainstem (midbrain, pons, medulla), cerebellum, and other locations. (3) Etiological classification: OCSP stroke classification [1] for ischemic stroke patients, including: Total Anterior Circulation Infarct (TACI), Partial Anterior Circulation Infarct (PACI), Posterior Circulation Infarct (POCI), Lacunar Circulation Infarct (LACI).

*Cerebral Hemorrhage and Location, Hemorrhage Volume:* (1) Diagnostic criteria: Refer to the *China Diagnostic Points for Major Cerebrovascular Diseases 2019* [15] formulated by the Neurology Branch of the Chinese Medical Association, meeting diagnostic points for cerebral hemorrhage. (2) Cerebral hemorrhage location: According to the *China Cerebrovascular Disease Classification (2015)*, locations include: basal ganglia hemorrhage, lobar hemorrhage, brainstem hemorrhage, cerebellar hemorrhage, and other locations. (3) Hemorrhage volume estimation: For cases without ventricular rupture, calculate hemorrhage volume (ml) as: (maximum length × maximum width × number of slices with hemorrhage) / 2 on brain CT.

*Swallowing Disorder:* Diagnostic criteria: Refer to the Scottish Intercollegiate Guidelines Network' s *National Clinical Guidelines for Stroke Patients: Identification and Treatment of Dysphagia*: inability to safely transport food or liquid from mouth to stomach, or causing aspiration.

*Complication Information:* Main complications include post-infarct hemorrhagic transformation, stroke-associated pneumonia, deep vein thrombosis, pulmonary embolism, cerebral edema, and increased intracranial pressure. Need to identify whether patients experienced these complications, specific dates of occurrence, and management. Diagnostic criteria refer to the *Expert Consensus on Core Data Elements and Definitions for Stroke Clinical Diagnosis and Disease Management* [1].

*Epilepsy:* Identifies whether patients developed epilepsy, date of occurrence, and management. Epilepsy is a chronic disease caused by sudden abnormal discharge of brain neurons leading to transient brain dysfunction. Diagnosis relies on history, clinical symptoms, and EEG examination.

*Urinary Tract Infection:* Identifies whether patients developed urinary tract infection, date of occurrence, and management. Urinary tract infection refers to pathogens directly invading the urinary tract, growing and reproducing in urine, and invading urinary tract mucosa or tissues causing damage. Diagnosis requires urinary symptoms and signs (frequency, urgency, dysuria, suprapubic pain and tenderness, fever, flank pain and percussion pain) with urine bacterial culture colony count $ 10^{5}$/ml. Other laboratory tests (leukocyturia, positive nitrate reduction test and/or leukocyte esterase) can also aid diagnosis.

*Post-Stroke Constipation:* Identifies whether patients developed post-stroke con-

stipation, date of occurrence, and management. Post-stroke constipation refers to new-onset or worsened constipation after stroke. Diagnostic criteria: Refer to the Rome IV criteria for functional constipation established by the Rome Committee in 2016: (1) Must include two or more of the following: >25% of bowel movements requiring straining; >25% of bowel movements with lumpy or hard stools; >25% of bowel movements with incomplete evacuation sensation; >25% of bowel movements with anorectal obstruction sensation; >25% of bowel movements requiring manual assistance; spontaneous bowel movements <3 times per week (average weekly number of complete spontaneous bowel movements: only autonomous bowel movements considered completely evacuated by the patient). (2) Rarely loose stools without laxatives. (3) Does not meet diagnostic criteria for irritable bowel syndrome. All functional gastrointestinal disorders must have symptom onset at least 6 months before diagnosis and meet symptom requirements within the past 3 months [16].

*Post-Stroke Urinary Dysfunction:* Identifies whether patients developed post-stroke urinary dysfunction, date of occurrence, and management. Post-stroke urinary dysfunction refers to urinary difficulty, frequency, retention, incontinence, or automatic urination that occurs after stroke and persists after stabilization in patients with normal pre-stroke urinary function; or significantly increased frequency (nocturia $ $4 times) and urgency after stabilization compared to pre-stroke, severely affecting quality of life [17].

*Pressure Ulcers:* Identifies whether patients developed post-stroke pressure ulcers, date of occurrence, and management. Diagnostic criteria: Refer to the 3rd edition of the international *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guidelines* jointly published by NPIAP and EPUAP in 2019. Pressure ulcers, also known as bedsores, are localized injuries to skin and/or subcutaneous tissue caused by pressure or pressure combined with shear force during prolonged bed rest after stroke, typically located over bony prominences but may also be related to medical devices or other objects [18]. Pressure injuries may be medical device-related and can occur not only on skin surfaces (bony prominence areas such as sacrum, ischial tuberosity, greater trochanter, heel) but also on mucous membranes, within or beneath mucosa [18].

*Malnutrition:* Identifies whether patients developed post-stroke malnutrition, date of occurrence, and management. Diagnostic criteria: Refer to the *Chinese Expert Consensus on Standardized Nutritional Management of Stroke* by the Chinese Stroke Nutritional Standardization Management Expert Committee in 2020. Malnutrition is a state of energy or nutrient deficiency caused by insufficient intake or utilization 障碍, leading to altered body composition and decreased physiological and mental function, potentially resulting in adverse clinical outcomes [19]. Diagnostic criteria: Meeting one or more of the following five conditions: >6% weight loss from admission weight by day 7; BMI <18.5 $kg/m^2$; serum albumin concentration <35 g/L; serum transferrin concentration <1.80 g/L; serum prealbumin concentration <10 mg/dl.

### 2.2 Examination Information Data Elements and Definitions

Stroke-related examination information data elements total 14 items (Table 4 ), primarily including imaging, ECG, and laboratory examinations. Imaging mainly involves cranial CT and MRI. Cranial CT plain scan is the first-choice imaging examination for suspected stroke patients, while MRI can effectively identify acute small infarcts and is essential for cerebral infarction localization and OCSP classification diagnosis [20]. Cranial CT and MRI are equally important for determining the presence, size, location, and hematoma expansion of acute cerebral hemorrhage [21]. ECG examination and dynamic monitoring serve as important means for judging stroke severity and prognosis, enabling timely identification of cardiac problems in stroke patients for early clinical intervention to protect cardiac function [22].

Laboratory examinations include the three major routine tests (blood, urine, stool), C-reactive protein, four lipid parameters, blood glucose, glycated hemoglobin, coagulation function, homocysteine, liver and kidney function, electrolytes, and myocardial enzymes. Blood routine mainly registers red blood cells, white blood cells, hemoglobin, platelet count, and percentages of neutrophils, lymphocytes, and monocytes. Reduced platelet count is a contraindication for intravenous thrombolysis and serves as a reference for selecting antiplatelet drugs after cerebral infarction. C-reactive protein (CRP) is an important factor affecting acute cerebral infarction prognosis, with elevated CRP levels increasing cerebrovascular event risk [23,24]. Coagulation dysfunction is also a contraindication for intravenous thrombolysis in stroke patients [25], and hyperfibrinolytic or hypercoagulable states increase the risk of cardiovascular and cerebrovascular diseases. Abnormal blood lipids also increase the risk of atherosclerotic cardiovascular disease [26], making effective lipid control crucial for preventing atherosclerosis-induced cardiovascular and cerebrovascular diseases. Complications such as gastrointestinal bleeding and renal injury (renal failure) are also common after stroke [27]. Routine urine and stool testing after stroke helps early identification, with abnormal urine protein being an important marker for renal injury [28] and increasing mortality [29]. Positive occult blood in stool is an important sign of gastrointestinal bleeding, with upper gastrointestinal bleeding being the most common and severe complication of stroke that can further worsen stroke patients' condition and greatly affect prognosis [30]. Blood glucose levels are closely related to neurological function recovery in elderly diabetic patients with stroke, and controlling blood glucose may better facilitate neurological recovery [31]. Elevated blood glucose is likely a response to stress and severity of cerebral hemorrhage and a marker of mortality risk [26]. In-hospital mortality in ischemic stroke patients increases with the number of electrolyte disturbances, indicating a cumulative effect of electrolyte disorders on short-term prognosis in ischemic stroke patients [32]. Detecting homocysteine levels and implementing effective interventions for stroke patients with hyperhomocysteinemia can effectively improve prognosis and reduce stroke recurrence [33].

**Table 4 Data Elements and Definitions of Auxiliary Inspection Information**

*Cranial CT/MRI:* Includes the first cranial CT/MRI examination report after this onset, Gregorian calendar dates of all imaging examinations performed, and detailed description of results [1]. Cerebral hemorrhage: cranial CT; Cerebral infarction: cranial CT or MRI.

*ECG Examination:* Gregorian calendar date of examination performed during hospitalization and detailed description of results. Twelve-lead automatic ECG examination.

*Blood Routine:* Mainly includes the following items: red blood cells (RBC), white blood cells (WBC), hemoglobin (HGB), platelets (PLT), neutrophil percentage (N%), lymphocyte percentage (L%), monocyte percentage (M%).

*Urine Routine:* Mainly includes: urine protein (PRO), urine glucose (GLU-U), ketone bodies (KET), urine leukocytes (LEU), urine occult blood (BLU), pH value (PH-U), urobilinogen (URO), bilirubin (BIL).

*Stool Routine + Occult Blood:* Mainly includes: red blood cells (RBC), white blood cells (WBC), stool occult blood (OB).

*C-Reactive Protein:* Plasma C-reactive protein (CRP).

*Blood Lipids:* Mainly includes: total cholesterol (TC), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C).

*Blood Glucose:* Venous fasting plasma glucose (FPG).

*Glycated Hemoglobin:* Plasma glycated hemoglobin (GHB).

*Coagulation Function:* Mainly includes: prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), fibrinogen (FIB), D-dimer (DD2).

*Homocysteine:* Plasma homocysteine (HCY).

*Liver and Kidney Function:* Mainly includes: total protein (TP), albumin (ALB), alanine aminotransferase (ALT/GPT), aspartate aminotransferase (AST/GOT), gamma-glutamyl transferase ($\gamma$-GT), blood urea nitrogen (BUN), serum creatinine (Cr), uric acid (UA).

*Electrolytes:* Mainly includes: sodium (Na), potassium (K), chloride (Cl), carbon dioxide combining power (TCO2), calcium (Ca), phosphorus (P), magnesium (Mg).

*Myocardial Enzymes:* Mainly includes: creatine kinase (CK), creatine kinase isoenzyme (CK-MB), lactate dehydrogenase (LDH), alpha-hydroxybutyrate dehydrogenase (HBDH), aspartate aminotransferase (AST).

### 2.3 Clinical Treatment Information Data Elements and Definitions

Clinical treatment information data elements include 18 items covering Western medicine treatment, TCM treatment, and rehabilitation treatment after onset.

**2.3.1 Western Medicine Treatment Information Data Elements** Western medicine treatment information data elements total 13 items (Table 5 ), primarily incorporating treatment recommendations from the *Chinese Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke 2018* and the *Guidelines for the Management of Spontaneous Intracerebral Hemorrhage in Adults 2007*. For ischemic stroke patients, general management and specific treatments are provided. General management includes oxygen therapy and respiratory support, cardiac monitoring and management, temperature control, blood pressure, blood glucose, and lipid control, and nutritional support. Specific treatments include improving cerebral blood circulation (intravenous thrombolysis, endovascular treatment, antiplatelet, anticoagulation, fibrinolysis, volume expansion, etc.), statins, and neuroprotection. For hemorrhagic stroke patients, routine monitoring, symptomatic treatment, intracranial pressure reduction, antiepileptic treatment, early mobilization and rehabilitation training, prevention of venous thromboembolism and pulmonary embolism, anticoagulation, and surgical treatments such as craniectomy for hematoma removal are performed.

**Table 5 Data Elements and Definitions of Western Medicine Treatment Information**

*Thrombolytic Therapy:* Identifies whether the patient received thrombolytic therapy after onset, referencing the *Chinese Guidelines for Intravenous Thrombolysis in Acute Ischemic Stroke 2016*.

*Endovascular Treatment:* Identifies whether the patient received endovascular treatment after onset, referencing the *Chinese Guidelines for Early Endovascular Intervention in Acute Ischemic Stroke 2018*, including intra-arterial thrombolysis, mechanical thrombectomy, and emergency angioplasty.

*General Management:* Referring to the *Chinese Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke 2018* formulated by the Disease Control Department of the Ministry of Health and the Neurology Branch of the Chinese Medical Association, and the *Guidelines for the Management of Spontaneous Intracerebral Hemorrhage in Adults (2007 Update)* by the American Heart Association/American Stroke Association Stroke Council, Hypertension Research Council, and Interdisciplinary Working Group on Quality of Care and Outcomes Research. Treatment includes oxygen therapy and respiratory support, cardiac monitoring and management, temperature control, blood pressure, blood glucose, and lipid control, and nutritional support.

*Other Specific Treatments:* Including antiplatelet, anticoagulation, fibrinolysis, volume expansion, collateral circulation improvement, nerve nutrition, blood pressure, blood glucose, and lipid control, and other neuroprotective treatments.

Specific medications refer to the *Expert Consensus on Core Data Elements and Definitions for Stroke Clinical Diagnosis and Disease Management* [1].

*Other Medications:* Identifies whether patients used medications other than those listed above.

**2.3.2 Traditional Chinese Medicine Treatment Information Data Elements** Mainly includes 4 data elements for acupuncture treatment, cupping therapy, herbal medicine treatment, and tuina therapy (Table 6 ). Acupuncture therapy records include first and last intervention times, acupuncture intervention hour (in traditional Chinese time), total number of acupuncture treatments, and types of acupuncture therapy. Acupuncture therapy references the *TCM Clinical Terminology - Treatment Methods Part 2020* issued by the National Administration of Traditional Chinese Medicine and National Health Commission [34].

The relationship between acupuncture intervention timing and stroke prognosis is documented in *Great Compendium of Acupuncture* (Volume 8): "When initially struck by wind with sudden collapse, abrupt loss of consciousness, phlegm congestion, unresponsiveness, and clenched jaw preventing medication administration, urgently use a three-edged needle to puncture the twelve Jing-well points on fingers to remove evil blood."The *Chinese Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke 2018* lists acupuncture and herbal medicine for acute ischemic stroke as Grade II and III recommendation evidence, respectively. Acupuncture is safe in treating acute stroke and can reduce mortality or disability rates at 6 months. Academician Shi Xuemin pioneered acupuncture manipulation quantification, establishing that the direction of acupuncture force, magnitude of force, duration of acupuncture, and interval between treatments are four key factors affecting acupuncture efficacy. Before registration began, this study developed the "National Key R&D Project 'Case Registry Study of Acupuncture Treatment for Stroke Disease' Stroke Acupuncture Treatment Plan Survey Form," including acupuncture manipulation, needling time, operation techniques, and treatment courses, to comprehensively collect acupuncture treatment plans for stroke disease from all registry sites. Acupuncture timing is also closely related to stroke prognosis. The *Suwen · Bazheng Minglun* states: "When weather is warm and days are bright, human blood flows smoothly and defensive qi floats, making blood easy to drain and qi easy to circulate···therefore regulating blood and qi according to seasonal timing." The *Suwen · Zangqi Fashi Lun* notes: "Treat according to the four seasons and five elements in accordance with human form." The *Suwen · Bazheng Minglun* states: "Follow the laws of heaven and earth, combine with celestial light···All needling methods must observe the sun, moon, stars, and the qi of the four seasons and eight solar terms, needling only when qi is stable." Therefore, different needling times produce different treatment effects for stroke.

**2.3.3 Cupping, Tuina, and Rehabilitation Treatment Information Data Elements** Cupping and tuina belong to the category of external TCM treatment methods. Cupping applied to stroke sequelae can promote local blood circulation and regulate brain function. The benign stimulation of cupping can relieve local vascular and smooth muscle spasms, improving cerebral hypoxia and thereby alleviating stroke-induced pain [35]. Tuina involves using TCM basic theory and various manipulation techniques to regulate the body and prevent disease. Through acupoint massage, kneading, and manipulation, tuina can effectively relieve limb pain in stroke patients, enhance limb function recovery, and improve quality of life [36].

Rehabilitation treatment data elements include definitions, types, and statistical methods for rehabilitation therapy (Table 6). Rehabilitation treatment refers to interventions that restore normal or near-normal physical and mental function or disability caused by injury, disease, or developmental defects. Data element definitions reference the *Common Rehabilitation Treatment Technology Operation Standards (2012 Edition)* issued by the Ministry of Health, the *Chinese Stroke Rehabilitation Treatment Guidelines (2011 Complete Edition)* published by the Neurological Rehabilitation Group of the Neurology Branch of the Chinese Medical Association, the Cerebrovascular Disease Group, and the Office of the Stroke Screening and Prevention Project of the Ministry of Health, and the *Clinical Guidelines for Physical Technology-Assisted Stroke Rehabilitation (2019)* by the Anti-Aging Branch of the China Information Association for Traditional Chinese Medicine. Rehabilitation treatment programs mainly include exercise therapy, occupational therapy, speech therapy, and physical factor therapy. Early systematic rehabilitation after stroke can effectively improve neurological symptoms and quality of life [37], and acupuncture combined with rehabilitation for stroke sequelae such as motor dysfunction and swallowing disorders shows significant advantages over rehabilitation or acupuncture alone [38,39].

**Table 6 Data Elements and Definitions of Clinical TCM Treatment Information**

*Acupuncture Treatment:*

First acupuncture intervention time: Includes the Gregorian calendar date and hour of the patient' s first acupuncture treatment after onset and the first acupuncture treatment during study participation.

Acupuncture intervention hour: According to Beijing time, one day and night are divided into 12 periods, each called a "hour" (shi). Identifies the hour of first acupuncture intervention after onset and during study participation. 1=Zi hour (23:00-01:00), 2=Chou hour (01:00-03:00), 3=Yin hour (03:00-05:00), 4=Mao hour (05:00-07:00), 5=Chen hour (07:00-09:00), 6=Si hour (09:00-11:00), 7=Wu hour (11:00-13:00), 8=Wei hour (13:00-15:00), 9=Shen hour (15:00-17:00), 10=You hour (17:00-19:00), 11=Xu hour (19:00-21:00), 12=Hai hour (21:00-23:00).

Last acupuncture intervention time: Identifies the Gregorian calendar date of

the patient' s last acupuncture treatment in each visit period, including during hospitalization and follow-up.

Total number of acupuncture treatments: Identifies the total number of acupuncture treatments in each visit period, including during hospitalization, from discharge to 3 months post-onset, 3-6 months post-onset, and 6-12 months post-onset.

Acupuncture therapy: Referencing the *TCM Clinical Terminology - Treatment Methods Part 2020* issued by the National Administration of Traditional Chinese Medicine and National Health Commission. Definition: Generally refers to therapies using specially made metal needles to stimulate acupoints with rotation, lifting, and thrusting techniques, or using moxa to warm acupoints, through dredging meridians, regulating viscera, or warming meridians, supporting yang and dispelling cold to prevent and treat disease. Specific types include: body acupuncture, scalp acupuncture, eye acupuncture, ear acupuncture, ear pressure therapy, tongue acupuncture, wrist-ankle acupuncture, intradermal needle therapy, three-edged needle therapy, elongated needle therapy, electroacupuncture, acupoint injection therapy (also called hydro-acupuncture), fire needle therapy, warm needle therapy, moxibustion, thunder-fire moxibustion, acupoint catgut embedding therapy, plaster therapy, small needle-knife therapy, and other therapies.

*Cupping Therapy:* Identifies whether patients received cupping therapy during the study and total number of treatments. Refers to external treatment methods using various cupping instruments to create negative pressure by removing air, adsorbing on skin surfaces, causing local congestion and blood stasis to stimulate meridians and acupoints or detoxify and drain pus for therapeutic effects.

*Herbal Medicine Treatment:* Identifies whether patients received herbal medicine treatment and records herbal prescription composition and dosage.

*Tuina Therapy:* Identifies whether patients received tuina training during the study and total number of treatments. Tuina therapy: Generally refers to therapies where doctors apply various manipulation techniques such as pushing, grasping, rubbing, and kneading on specific body areas or acupoints, sometimes combined with specific limb activities, to prevent disease and promote rehabilitation.

*Rehabilitation Treatment:* Referencing the *Common Rehabilitation Treatment Technology Operation Standards (2012 Edition)* issued by the Ministry of Health and the 2019 *Clinical Guidelines for Physical Technology-Assisted Stroke Rehabilitation.* Identifies whether patients received rehabilitation treatment after onset and rehabilitation treatment status during the study. Records the date of rehabilitation treatment and rehabilitation programs: exercise therapy, occupational therapy, speech therapy, physical factor therapy. Each treatment use/type is recorded once, with total counts recorded separately (e.g., exercise therapy total 1 time, physical factor therapy total 2 times—including phototherapy 1 time, electrotherapy 1 time).

## 3. Outcome Information Data Elements for Stroke Patients

Outcome information data elements total 8 items (Table 7 ), evaluating relevant scales at patient admission, discharge, and follow-up periods to assess baseline status, quality of life, and neurological recovery after onset. These include Modified Rankin Scale (mRS) score shift, recurrent cardiovascular and cerebrovascular events, NIH Stroke Scale (NIHSS) score, 5-level EuroQol Five Dimensions questionnaire (EQ-5D-5L), Functional Oral Intake Scale (FOIS), and safety indicators including acupuncture adverse reactions, adverse events, or serious adverse events. The mRS is used to evaluate daily living ability during stroke recovery to assess prognosis and is the most commonly used scale for evaluating stroke outcomes. The NIHSS is one of the strongest predictors of early mortality risk, covering both anterior and posterior circulation as an objective semi-quantitative tool for stroke severity evaluation, widely used in international multicenter randomized controlled studies with good reproducibility [40]. The EQ-5D-5L is the recommended optimal tool by the UK' s National Institute for Health and Clinical Excellence (NICE) for evaluating Health-Related Quality of Life (HRQOL), with good reliability, validity, and sensitivity. It can evaluate changes in stroke patients'quality of life before and after treatment, and through indirect measurement of health utility values, obtain Quality-Adjusted Life Years (QALYs) for cost-utility analysis, providing optimal decision support for acupuncture treatment selection in stroke patients. Early screening and risk assessment of swallowing disorders in stroke patients are significant for comprehensively grasping disease progression trends and preventing aspiration. Definitions for other related data elements adopt those in national health industry standards.

**Table 7 Data Elements and Definitions of Stroke Patient Outcome Information**

*Modified mRS Score:* The mRS has 7 grades, with 0 representing no symptoms and higher scores indicating worse prognosis; 6 represents death. For prognosis evaluation, scores $ $2 indicate good outcome [41]. mRS score shift: Counts the number of patients at each mRS score point at each observation time point; lower scores with more patients indicate better treatment effects.

*NIHSS Score:* The scale includes assessment of consciousness, language, motor function, sensation, coordination, eye movement, and visual fields, scored 0-42 [42], with higher scores indicating more severe neurological deficits. 0-4: mild stroke/minor stroke; 5-20: moderate to severe stroke; 20-42: severe stroke.

*EQ-5D-5L Score:* The EQ-5D-5L includes mobility, self-care, and daily activity abilities, plus two dimensions representing physical and emotional states: pain/discomfort and anxiety/depression. The scale has five dimensions, each with five severity levels from mild to severe (recorded as 1, 2, 3, 4, 5). The UK time trade-off (TTO) utility value conversion table is used to calculate EQ-5D-5L index scores.

*FOIS Score:* This assessment is conducted for patients with concomitant swallowing disorders. The FOIS has 7 levels, with lower levels indicating worse swallowing function [43]. It reflects swallowing function multidimensionally from food texture (single or multiple types), process (special preparation or compensation), and method (oral or nasogastric feeding).

*Recurrent Cardiovascular and Cerebrovascular Events:* Refers to reoccurrence of acute cerebral infarction, acute cerebral hemorrhage, or acute myocardial infarction after this onset. Identifies whether patients experienced recurrent cardiovascular and cerebrovascular events (stroke recurrence, hemorrhage recurrence, myocardial infarction) and the Gregorian calendar date of occurrence, supported by cranial CT/MRI or ECG examination with recorded reports.

*Acupuncture Adverse Reactions:* Referring to the definition of adverse events in the *Real-World Acupuncture Case Registry Study Management Standards*, identifies whether patients experienced acupuncture adverse reactions, records the Gregorian calendar date, whether treatment was administered, and outcome. Acupuncture adverse reaction descriptions include: needle fainting, needle stagnation, needle breakage, bent needle, abnormal post-needling sensation, bleeding, subcutaneous hematoma, pneumothorax, visceral injury, nerve injury, rash, burn, other.

*Adverse Events or Serious Adverse Events:* Referring to the definition of adverse events in *Chinese Good Clinical Practice for Drug Clinical Trials*, identifies whether patients experienced adverse events or serious adverse events, records the Gregorian calendar date, whether treatment was administered, and outcome. Adverse events refer to adverse medical events occurring during the study period, not necessarily causally related to treatment, manifested as symptoms, signs, diseases, or abnormal laboratory results, including accidents such as fractures or traffic accidents. Serious adverse events refer to death, life-threatening events, hospitalization or prolonged hospitalization, permanent or significant disability/functional loss, congenital anomaly, or other important medical events occurring during the study period. If patient death occurs after onset, detailed records of the Gregorian calendar date, time, and cause of death are required.

## 4. Discharge and Follow-up Information Data Elements for Stroke Patients

Patient discharge involves main diagnosis, hospitalization days, related costs (total hospitalization costs, out-of-pocket expenses, and acupuncture costs), discharge method and destination, and attending physician information. Follow-up periods mainly include disease progression, medication use, and related costs (total costs, out-of-pocket expenses, and acupuncture costs for stroke and its sequelae and complications). Comprehensive discharge and follow-up data elements total 10 items (Table 8 ), used for evaluating patient hospitalization/follow-up outcomes [1]. Hospital treatment physician information including employee ID, gender, professional title, and years of acupuncture practice are used to analyze

factors influencing patient outcomes. The following data elements and definitions refer to the *Basic Medical Record Writing Standards* issued by the Ministry of Health in 2002.

**Table 8 Data Elements and Definitions of Discharge and Follow-up Information**

*Main Diagnosis:* The name of the clinical diagnosis of the disease suffered by the individual in a specific classification system.

*Hospitalization Days:* The difference between discharge date and admission date minus 1 for this hospitalization.

*Hospitalization Costs/Yuan:* Total costs during this hospitalization after stroke.

*Hospitalization Acupuncture Costs/Yuan:* Total acupuncture costs (content refers to Appendix 6 acupuncture therapy) during the same hospitalization.

*Out-of-Pocket Hospitalization Costs/Yuan:* Total out-of-pocket expenses during the same hospitalization.

*Follow-up Costs/Yuan:* Total costs during the follow-up period after this stroke discharge.

*Follow-up Acupuncture Costs/Yuan:* Total acupuncture costs (content refers to Appendix 6 acupuncture therapy) during the follow-up period after discharge.

*Discharge Method:* Doctor' s order discharge, self-discharge, doctor' s order transfer, non-doctor' s order transfer, other.

*Discharge Destination:* Home, transfer to other hospital, transfer to community hospital, transfer to rehabilitation center, other.

*Physician Information:*
- Employee ID: Physician' s employee number in their institution.
- Gender: According to national health industry standards, includes male, female, unspecified gender, unknown gender.
- Professional Title: Physician' s professional technical position qualification, including junior, intermediate, deputy senior, and senior titles.
- Years of Acupuncture Practice: Time from obtaining medical practice license to engaging in acupuncture treatment for the patient.

## 5. Summary

The "International Acupuncture Case Registry Platform Project (www.amreg.org)" was jointly supported and launched by the China Association of Acupuncture and Moxibustion and the World Federation of Acupuncture-Moxibustion Societies. On February 11, 2017, the establishment of the China Association of Acupuncture and Moxibustion Acupuncture Case Registry Research Alliance marked the official launch of the first international large-scale real-world

acupuncture study [44]. In 2020, the *Expert Consensus on Core Data Elements and Definitions for Stroke Clinical Diagnosis and Disease Management* organized by the National Clinical Research Center for Neurological Diseases integrated the latest stroke treatment guidelines and international data element definition literature, defining and standardizing stroke-related data to provide references for developing stroke clinical research variables [1], facilitating standardized data collection, clinical diagnosis and treatment normalization, and data sharing for stroke clinical research and treatment, promoting big data technology application in this field [45]. In 2021, the *Real-World Acupuncture Case Registry Study Management Standards* (Group Standard: T/CAAM 00XX-2021) compiled by the China Association of Acupuncture and Moxibustion stipulated management methods for real-world acupuncture case registry studies to ensure research quality, representing a scientific research management standard in the real-world acupuncture clinical research standard system and providing important references for conducting real-world acupuncture clinical research.

The "Data Elements and Definitions for the Case Registry Study of Acupuncture Treatment for Stroke Disease" selected 9 core datasets covering stroke from onset, treatment, outcome, and follow-up. This data standard is based on the *Expert Consensus on Core Data Elements and Definitions for Stroke Clinical Diagnosis and Disease Management* and the *Real-World Acupuncture Case Registry Study Management Standards*, including demographic information, past history and risk factors, clinical symptoms and signs and complication information, auxiliary examinations, Western medicine treatment, TCM treatment, rehabilitation treatment, outcome information, and discharge and follow-up information. Standard data element definitions were developed, adding TCM four diagnostic information, acupuncture therapy, intervention timing, total number of acupuncture treatments, etc., providing data support for studying acupuncture dose-effect relationships and highlighting TCM and acupuncture characteristics, offering references for conducting real-world TCM acupuncture research.

Based on thorough review of relevant standards, guidelines, and expert consensus, aligned with contemporary mainstream trends and closely integrated with research objectives and content combined with TCM acupuncture characteristics, the research group developed this project' s data elements and definitions. All 31 research group members from participating institutions received unified training to ensure consistency in data definitions. Through application of standardized data elements, registry data quality can be efficiently guaranteed, providing assurance for data processing and mining, promoting interconnectivity of stroke disease and complication diagnosis and treatment data across the national acupuncture center collaborative network and the national acupuncture field. This facilitates the conduct of clinical registry studies and other real-world stroke studies. It is hoped that these data elements and definitions will provide standardized data elements for real-world acupuncture clinical research, assist in data collection and information integration for stroke clinical research,

and further promote standardization of medical quality assessment and multi-center large-sample randomized controlled or real-world studies for stroke and acupuncture/TCM treatment. We anticipate the development of related expert consensus and guidelines to improve clinical research quality and promote continuous improvement in medical quality.

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*Note: Figure translations are in progress. See original paper for figures.*