Development of Quality Indicators of Stroke Centers and Feasibility of Their Measurement Using a Nationwide Insurance Claims Database in Japan
— J-ASPECT Study —

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Background: We aimed to develop quality indicators (QIs) related to primary and comprehensive stroke care and examine the feasibility of their measurement using the existing Diagnosis Procedure Combination (DPC) database.

Methods and Results: We conducted a systematic review of domestic and international studies using the modified Delphi method. Feasibility of measuring the QI adherence rates was examined using a DPC-based nationwide stroke database (396,350 patients admitted during 2013–2015 to 558 hospitals participating in the J-ASPECT study). Associations between adherence rates of these QIs and hospital characteristics were analyzed using hierarchical logistic regression analysis. We developed 17 and 12 measures as QIs for primary and comprehensive stroke care, respectively. We found that measurement of the adherence rates of the developed QIs using the existing DPC database was feasible for the 6 QIs (primary stroke care: early and discharge antithrombotic drugs, mean 54.6% and 58.7%; discharge anticoagulation for atrial fibrillation, 64.4%; discharge antihypertensive agents, 51.7%; comprehensive stroke care: fasudil hydrochloride or ozagrel sodium for vasospasm prevention, 86.9%; death complications of diagnostic neuroangiography, 0.4%). We found wide inter-hospital variation in QI adherence rates based on hospital characteristics.

Conclusions: We developed QIs for primary and comprehensive stroke care. The DPC database may allow efficient data collection at low cost and decreased burden to evaluate the developed QIs.

Key Words: Cerebrovascular disease; Performance measure; Quality and outcomes; Quality indicator; Stroke

In Japan, stroke is the 3rd leading cause of death and a leading cause of long-term disability. Recently, the quality of acute stroke care has received increasing attention worldwide. In the USA, several healthcare organizations have undertaken initiatives related to measuring and improving the quality of acute stroke care. In 2000, the American College of Cardiology/American Heart Association (ACC/AHA) published a report on the quality indicator (QI) of care for cardiovascular disease and stroke patients.1 The Brain Attack Coalition published guidelines for

Received February 12, 2019; revised manuscript received August 7, 2019; accepted August 14, 2019; J-STAGE Advance Publication released online September 26, 2019  Time for primary review: 84 days
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Close The Gap–Stroke in J-ASPECT Study

Methods

Procedures and Definitions of QIs for PSCs and CSCs

A standardized process for developing QIs was initiated by the research committee in 2015. They aimed to develop QIs for PSCs and CSCs that reflected basic (e.g., rt-PA therapy for acute ischemic stroke) and advanced (e.g., endovascular therapy for acute ischemic stroke or surgical treatment of hemorrhagic stroke) stroke care. Our method for developing these QIs was adapted from the RAND-University of California, Los Angeles Appropriateness Method (modified Delphi method).12 This method involved the preparation of candidate QIs and a summarization of supporting evidence, followed by examination by a group of experts to determine whether these QIs had clinical validity and feasibility.

For the candidate QIs for PSCs, we performed systematic reviews of domestic and international studies. The search strategy identified articles published from 1990 to 2014 in MEDLINE. Key search terms included “Cerebrovascular Disorders” AND “Quality Indicators, Health Care” OR “Management Audit” OR “Process Assessment (Health Care)”. In addition, we referred to the Japanese guidelines for stroke care13 and existing QIs from other countries14–16 for the selection of QI candidates.

As for the candidate QIs for CSCs, we focused on the core metrics of the Joint Commission,14 and further selected candidates from the Class I Recommendations in the 2015 updated AHA/ASA guidelines for acute ischemic stroke regarding endovascular treatment.17 We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.15

We invited a multidisciplinary panel of 17 experts in the field of methodological QI development, acute stroke care, neurosurgery, neurology, endovascular surgery, and rehabilitation to assess the validity of the candidate indicators using the modified Delphi method. The QIs that received high ratings after a detailed face-to-face discussion remained in the final set (Supplementary Table 2).

Measurement of the Defined QIs Using the Nationwide DPC Database

As the initial step of this initiative, we sought to determine the feasibility of measuring the adherence rates of the developed QIs using the existing DPC database in the J-ASPECT Study to reduce the burden on hospitals. Of the 1,369 certified training institutions of the Japan Neurosurgical Society and the Japan Stroke Society, 558 hospitals responded to the DPC survey. Enrollment in the J-ASPECT study has increased progressively from January 2010 (Figure 1). The J-ASPECT study group has analyzed the DPC database to gain new clinical insights, an approach...
we applied again for this cross-sectional survey. Details of the J-ASPECT study are reported elsewhere. Briefly, the DPC is a mixed-case patient classification system that was launched in 2002 by the Japanese Ministry of Health, Labor, and Welfare and linked to hospitals’ financing system. The DPC database includes data on all patients admitted to participating hospitals, including each patient’s profile (age, sex and level of consciousness at admission according to the Japan Coma Scale), principal diagnoses, comorbidities on admission, and complications after admission (coded by the International Classification of Diseases and Injuries, 10th revision); procedures including surgeries, medications, and devices used during hospitalization; length of stay; discharge status; and medical expenses. We used the DPC data generated during routine clinical practice in the J-ASPECT study as in other nationwide studies using DPC data. To maximize the accuracy of the DPC data in the mixed-case patient classification system, at least one responsible physician (e.g., physicians in charge or residents) were required to record the information with respect to diagnoses and therapies on each patient’s medical chart. In the 2014 institutional survey of the J-ASPECT study, the mean numbers of board-certified physicians were 4, 3, 2, and 1 for the Japan Neurosurgical Society, the Japan Stroke Society, the Japanese Board of Neurology, and the Japanese Society for Neuroendovascular Therapy, respectively (unpublished observation). Responsible physicians in each hospital were not specifically recruited for the J-ASPECT study. The high validity of diagnoses and procedures has been reported by previous studies. The adherence rates in each institution were classified as high (≥75%), intermediate (75–50%), or low (<50%) for descriptive purposes. Further, associations between adherence rates and hospital characteristics (no. of annual hospital discharge and beds, academic status (university vs. non-university hospital), and CSC capability (CSC score)) were analyzed using hierarchical logistic regression analysis adjusted for age, sex, and severity (Japan Coma Scale score). The CSC score is the hospital’s capability as a CSC; that is, total number of fulfilled recommended items for certification of CSC by the Brain Attack Coalition.13

Ethics Statement
This study was approved by the Kyushu University Institutional Review Board, which waived the requirement for informed consent from the participants.

Statistical Analysis
All continuous variables are presented as mean±SD or median (interquartile range; IQR) for variables with a skewed distribution. Analysis of variance was used to compare the means across multiple groups. Non-continuous and categorical variables are presented as frequencies or percentages, and were compared using the \( \chi^2 \) test. We also examined the yearly QI compliance rates using the Cochran-Armitage trend test. The Bonferroni method was used to adjust the P-values in multiple testing, where appropriate. Hierarchical logistic regression analysis was used to investigate the associations of hospital characteristics (no. of stroke discharges [≥301 or not], no. of beds [≥300 or not], hospital type [academic or not], and CSC score [per 1-unit increase]) with QIs (PSC8, PSC9, PSC10, PSC12, and CSC12), adjusted for sex, age, and level of consciousness on admission according to the Japan Coma Scale. P<0.05 was considered to be statistically significant. The analyses were performed using SAS 9.4 (SAS Institute, Cary, NC, USA) and STATA 14 (Stata Corp, College Station, TX, USA).
QIs for PSCs
After the PUBMED database was screened, a total of 440 abstracts related to basic care of ischemic and hemorrhagic stroke or transient ischemic attacks (TIA) were identified (Supplementary Figure). In addition, 7 records for basic stroke care were identified from the guidelines of Japan and other countries.47–49 Of these, 184 publications were analyzed in detail, 29 articles were selected on the basis of evidence of their relevance (Supplementary References), and 19 potential indicators were selected as candidate QIs for PSCs. Finally, 17 QIs were selected after discussion by the expert panel (Table 1).

Table 1. Quality Indicators Selected for the Close the Gap-Stroke Program

| Indicator | Target population (denominator) | Treated patients (numerator) | Variable statement |
|-----------|---------------------------------|-------------------------------|-------------------|
| 1. NIHSS documentation | Patients with ischemic stroke | NIHSS score documented at the time of the initial admission note |
| 2. CT/MRI within 25 min of arrival | Patients with ischemic stroke arriving within 3.5 h of symptom onset | CT/MRI performed within 25 min of arrival |
| 3. CT/MRI within 24 h of arrival | Patients with any type of stroke | CT/MRI performed within 24 h of arrival |
| 4. Extracranial carotid artery evaluation | Patients with ischemic stroke/TIA | Extracranial carotid artery evaluated by carotid ultrasonography or angiography (CTA or MRA or DSA) |
| 5. Stroke Unit | Patients with any type of stroke | Treatment in Stroke Unit |
| 6. Intravenous thrombolysis administration | Patients with ischemic stroke arriving within 3.5 h of symptom onset | Intravenous thrombolysis performed |
| 7. Intravenous thrombolysis within 1 h of arrival | Patients with ischemic stroke who were administered intravenous thrombolysis | Intravenous thrombolysis performed within 1 h of arrival |
| 8. Antiplatelet within 48 h of onset | Patients with ischemic stroke/TIA | Antiplatelet therapy within 48 h of stroke onset |
| 9. Discharge on antiplatelet medication | Ischemic stroke/TIA patients | Antiplatelet medication prescribed at discharge |
| 10. Discharge on anticoagulation for AF | Ischemic stroke/TIA patients with atrial fibrillation | Anticoagulation prescribed at discharge |
| 11. Discharge on statin medication | Ischemic stroke/TIA patients with LDL ≥120 mg/dL | Statin prescribed at discharge |
| 12. Discharge on antihypertensive medication | Any type of stroke patient with hypertension | Antihypertensive agents prescribed at discharge |
| 13. DVT prophylaxis | Patients with any type of stroke | Foot-pumping for DVT performed within 2 days of arrival |
| 14. Dysphagia screening | Patients with any type of stroke | Dysphagia screening performed during hospital stay |
| 15. Rehabilitation | Patients with any type of stroke | Physiotherapy or occupational therapy performed within 2 days of arrival |
| 16. Smoking cessation | Patients with any type of stroke | Smoking cessation advice or counseling given during hospital stay |
| 17. Stroke education* | Patients with any type of stroke | Stroke education given during hospital stay |

(Table 1 continued the next page.)
**QIs for comprehensive stroke care**

| Indicator | Target population (denominator) | Treated patients (numerator) | Variable statement |
|-----------|---------------------------------|-----------------------------|--------------------|
| 1. Median time to multimodal CT or MR brain and vascular imaging | Patients with ischemic stroke arriving within 6h of the time that they were last known to be at baseline | Median time from arrival to start of multimodal CT or MR brain and vascular imaging (MRI/MRA or CT/CTA) | Exclusion: <18 years of age |
| 2. Received endovascular recanalization properly | Patients with ischemic stroke who were appropriate candidates for endovascular recanalization<br>Exclusion: <18 years of age | Endovascular recanalization procedure performed | |
| 3. Intravenous thrombolysis before endovascular recanalization | Patients with ischemic stroke who underwent endovascular recanalization procedure (arrived within 3.5h of symptom onset) | Intravenous thrombolysis performed | Exclusion: <18 years of age |
| 4. TICI grade 2b or 3 after endovascular recanalization | Patients with ischemic stroke who underwent endovascular recanalization procedure | Endovascular recanalization procedure performed with post-reperfusion TICI grade 2b or 3 | Exclusion: <18 years of age |
| 5. Median time of DTP | Patients with ischemic stroke who underwent endovascular recanalization procedure | Median time from door to puncture for patients who underwent the endovascular recanalization procedure | Exclusion: <18 years of age |
| 6. Symptomatic intracranial hemorrhage after thrombolytic or endovascular therapy | Patients with ischemic stroke who underwent endovascular recanalization or intravenous thrombolysis | Symptomatic intracranial hemorrhage developed within 36h after thrombolytic or endovascular therapy | Exclusion: <18 years of age |
| 7. 90-day mRS score documentation after thrombolytic or endovascular therapy | Patients with ischemic stroke who underwent thrombolytic or endovascular therapy | 90-day mRS score documented | Exclusion: <18 years of age, death during hospital stay |
| 8. Initial severity measure documentation | Patients with SAH or ICH | Initial severity measures documented | Exclusion: <18 years of age |
| 9. SAH intervention within 72h of onset | Patients with SAH who arrived within 48h of onset | Coiling or clipping procedure started within 72h of onset | Exclusion: <18 years of age, death within 2 days after onset |
| 10. Fasudil hydrochloride or ozagrel sodium administration for vasospasm | Patients with SAH who underwent the coiling or clipping procedure | Fasudil hydrochloride or ozagrel sodium administrated | Exclusion: <18 years of age, death within 2 days after onset |
| 11. PT-INR reversal for warfarin-associated ICH | Patients with warfarin-associated ICH and an elevated PT-INR (INR 1.4) | PT-INR reversal with a procoagulant preparation | Exclusion: <18 years of age |
| 12. Complication of diagnostic neuroangiography | Patients with any type of stroke | Stroke or death within 24h of diagnostic neuroangiography | Exclusion: <18 years of age, patients who underwent endovascular recanalization procedure |

*Information about activation of emergency medical system, follow-up after discharge, medications prescribed at discharge, risk factors for stroke and warning signs and symptoms of stroke. †Patients who meet all the following criteria: pre-stroke mRS score 0–1, acute ischemic stroke receiving intravenous r-tPA within 4.5h of onset according to guidelines from professional medical societies, causative occlusion of the ICA or proximal MCA (M1), NIHSS score ≥6, ASPECTS ≥6, treatment can be initiated (groin puncture) within 6h of symptom onset. AF, atrial fibrillation; CT, computed tomography; CTA, computed tomography angiography; DSA, digital subtraction angiography; DTP, door to puncture; DVT, deep vein thrombosis; ICH, intracerebral hemorrhage; INR, international normalized ratio; LDL, low-density lipoprotein; MRA, magnetic resonance angiography; MRI, magnetic resonance imaging; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; TIA, transient ischemic attacks; SAH, subarachnoid hemorrhage; TICI, Thrombolysis in Cerebral Infarction.*

The QI domains comprised documentation of the initial severity measure (Indicator 1), diagnosis (Indicator 2–4), coordination of care (Indicator 5), acute medication (Indicators 6–8), initiation of secondary prevention for recurrent stroke (Indicators 9–12), prevention of complications (e.g., aspiration pneumonia, venous thromboembolism) (Indicators 13, 14), rehabilitation (Indicator 15), and patient education (Indicators 16, 17).

**QIs for CSCs**

For the CSCs, 14 potential indicators were selected and finally, 12 QIs were selected (Table 1). The QI domains...
onset was approximated by the proportion of patients on antiplatelet drugs administered within 2 days of urgent admission in this feasibility study. Adherence rates in patients for the 6 QIs are shown in Table 4 and Figure 2A–E. The adherence rates for patients with ischemic stroke/TIA were intermediate for administered antiplatelet drugs within 2 days of urgent admission (54.6%), antiplatelet drugs at discharge (58.7%), and anticoagulation for atrial fibrillation at discharge (64.4%). The adherence rates of antihypertensive medication for patients with hypertension were intermediate in ICH patients (60.5%), whereas those for patients with other types of stroke/TIA were low (49.2% for ischemic stroke/TIA, 43.7% for SAH). The administration of fasudil hydrochloride or ozagrel sodium for vasospasm was high (86.9%). The occurrence of fatal complications with diagnostic neuroangiography was very low (0.4%) (Table 4).

Association Between QI Adherence and Hospital Characteristics

The association between selected QI adherence and hospital characteristics is shown in Table 5. Odds ratios represent the degree of high adherence to each QIs (PSCs: 8, 9, 10, 12) or the risk of complication (CSC 12) for hospital characteristics. A higher number of stroke discharges (≥301) and higher CSC score were significantly associated with high adherence to the defined QIs. The measurement of the developed QIs using the existing DPC database was feasible for the following 6 QIs: 4 for PSCs (Indicators 8, 9, 10 and 12) and 2 for the CSCs (Indicators 10 and 12). Because of the lack of time metrics in the DPC database, the adherence rate for administered antiplatelet drugs within 48 h of onset was approximated by the proportion of patients on antiplatelet drugs administered within 2 days of urgent admission in this feasibility study. Adherence rates in patients for the 6 QIs are shown in Table 4 and Figure 2A–E. The adherence rates for patients with ischemic stroke/TIA were intermediate for administered antiplatelet drugs within 2 days of urgent admission (54.6%), antiplatelet drugs at discharge (58.7%), and anticoagulation for atrial fibrillation at discharge (64.4%). The adherence rates of antihypertensive medication for patients with hypertension were intermediate in ICH patients (60.5%), whereas those for patients with other types of stroke/TIA were low (49.2% for ischemic stroke/TIA, 43.7% for SAH). The administration of fasudil hydrochloride or ozagrel sodium for vasospasm was high (86.9%). The occurrence of fatal complications with diagnostic neuroangiography was very low (0.4%) (Table 4).

Table 2. Characteristics of Patients From the J-ASPECT Study Discharged Between 2013 and 2015

| Age (years), median (IQR) | Overall cohort (n=396,350) | Ischemic stroke/TIA (n=266,475) | Intracerebral hemorrhage (n=99,658) | Subarachnoid hemorrhage (n=30,217) | P value |
|---------------------------|-----------------------------|---------------------------------|----------------------------------|----------------------------------|---------|
| Female (%)                | 43.8                        | 41.7                            | 42.2                             | 67.3                             | <0.001  |
| Ambulance use (%)         | 57.8                        | 51.2                            | 69.6                             | 76.7                             | <0.001  |

Table 3. Characteristics of Hospitals Participating in the J-ASPECT Study Between January 2013 and December 2015

| Hospital characteristics | Overall cohort (n=558) | 2013 (n=439) | 2014 (n=419) | 2015 (n=451) | P value |
|--------------------------|------------------------|--------------|--------------|--------------|---------|
| No. of stroke discharges (%) |            |              |              |              |         |
| >301                      | 36.9                   | 39.2         | 44.2         | 42.6         | <0.001  |
| 101–300                   | 46.6                   | 44.0         | 47.3         | 49.7         |         |
| 0–100                     | 16.5                   | 16.9         | 8.6          | 7.8          |         |
| No. of beds               | 405.5 (279.2–585)      | 430.0 (300.5–609) | 430 (294.5–605) | 413.0 (284–600) | 0.164   |
| Hospital type (%)         | Non-academic           | 86.4         | 84.7         | 84.5         | 85.6    | 0.685   |
|                           | Academic               | 13.6         | 15.3         | 15.5         | 14.4    |         |
### Table 4. Adherence Rates for PSC and CSC QIs in Patients in the Overall Cohort and for Specific Stroke Types

| Indicator | Target population | No. of eligible patients | Adherence rates (CSC12: complication rates) (%) |
|-----------|-------------------|--------------------------|-----------------------------------------------|
| 8. Antiplatelet within 2 days of urgent hospitalization* | Ischemic stroke/TIA | 265,034 | 54.6 |
| 9. Discharge on antiplatelet medication | Ischemic stroke/TIA | 212,080 | 58.7 |
| 10. Discharge on anticoagulation for AF | Ischemic stroke/TIA | 40,977 | 64.4 |
| 12. Discharge on antihypertensive medication | Overall stroke patients with hypertension | 185,996 | 51.7 |
| | Ischemic stroke/TIA patients with hypertension | 126,185 | 49.2 |
| | ICH patients with hypertension | 47,634 | 60.5 |
| | SAH patients with hypertension | 12,177 | 43.7 |
| 10. Fasudil hydrochloride or ozagrel sodium administration for vasospasm | SAH | 16,415 | 86.9 |
| 12. Death complication of diagnostic neuroangiography | Overall | 27,703 | 0.4 |
| | Ischemic stroke/TIA | 14,032 | 0.2 |
| | ICH | 5,031 | 0.2 |
| | SAH | 8,640 | 0.7 |

*The adherence rate of this QI was the approximated value for antiplatelet drugs administered 48h of onset in this feasibility study. CSC, comprehensive stroke center; ICH, intracerebral hemorrhage; PSC, primary stroke center; SAH, subarachnoid hemorrhage; TIA, transient ischemic attack.

### Figure 2

Adherence rates by hospitals for the selected 6 QIs using the DPC database. (A) PSC8, antiplatelet drugs within 48h of onset; (B) PSC9, discharge on antiplatelet medication; (C) PSC10, discharge on anticoagulation for atrial fibrillation; (D) PSC12, discharge on antihypertensive medication; (E) CSC10, fasudil hydrochloride or ozagrel sodium administration for vasospasm; (F) CSC12, death complication of diagnostic neuroangiography. CSC, comprehensive stroke center; DPC, Diagnosis Procedure Combination; QI, quality indicator; PSC, primary stroke center.
with greater adherence to administered antiplatelet drugs within 48 h of onset, antiplatelet drugs at discharge, and anticoagulation for atrial fibrillation at discharge, whereas a higher number of beds (≥300) had no relation to any higher adherence. Academic institutions were associated with higher adherence to antihypertensive medication for patients with hypertension.

Discussion

The present study describes the development of the CTGS initiative, the first nationwide quality improvement initiative in Japan. This initiative primarily aimed to develop and implement evidence-based indicators for measuring the quality of acute hospital stroke care in Japan. The major findings were as follows. (1) As the first stage, we developed 17 and 12 QIs for PSCs and CSCs, respectively, using a traditional method. (2) Among these QIs, we found successful measuring of adherence rates of 4 and 2 QIs for PSCs and CSCs, respectively, using the existing J-ASPECT DPC database. (3) We found wide inter-hospital variations in adherence rates of QIs in the domains of acute medication and initiation of secondary prevention, which were associated with the number of stroke discharges, comprehensive stroke care capabilities, and academic status.

Development of QIs for PSCs and CSCs

Although the certification of PSCs and CSCs is now in rapid progress worldwide, the gap between clinical evidence and practice is largely unexplored. Thus, we developed the QIs to continuously measure the quality of stroke care at PSCs or CSCs to close such evidence-practice gaps in Japan. After certification of PSCs and CSCs, probably based on the recommended structural items, the study group will encourage the PSCs and CSCs to report annually their adherence rates for the 17 QIs (for PSCs) and all of the 29 QIs (for PSCs and CSCs), respectively, to enable international comparison and continuous improvement of the quality of stroke care.

Measuring the Adherence Rates of the Selected QIs Using the J-ASPECT DPC Database

Unlike registries’ activities, quality improvement-based activities do not usually have a continuous source of funding, so the issue of sustainability is important. Further, the various QI programs such as GWTG also rely on data that must be collected prospectively or manually extracted from medical records. Although higher quality care, such as increased use of intravenous rt-PA infusion and mechanical thrombectomy, in the acute stroke setting might lead to measurable cost savings, the costs associated with data collection and quality improvement are difficult to quantify. Here we found that the feasibility and validity of measuring adherence rates of 6 of the 29 defined QIs with no significant additional time and cost using the existing DPC-based data collected for the J-ASPECT study suggested the potential sustainability of this initiative.

We found great variations in the adherence rates for the 6 QIs, mainly in the domains of acute medication and initiation of secondary prevention for ischemic stroke and TIA, among the participating hospitals in Japan. The present finding is consistent with the results in the field of cardiovascular medicine in Japan using DPC data (the Japanese Registry Of All cardiac and vascular Diseases). Such approaches may contribute to improving the quality of care more efficiently by targeting hospitals with low adherence rates for selected QIs in the fields of cardiovascular medicine and stroke.

International Comparison of the Adherence Rates for QIs

In the context of international comparison, the adherence rates of antiplatelet administration within 48 h of onset, discharge on antiplatelet medication, and discharge on anticoagulation for atrial fibrillation were almost over 95% according to the data of the Joint Commission (US) between 2011 to 2015. In European countries, the rate of discharge on antiplatelet medication was high, ranging from 85% to 95%, from 2004 to 2009, although the rate of discharge on anticoagulation for atrial fibrillation was low (25–50%). In the present study, the adherence rates for antiplatelet administration within 48 h of onset and discharge on antiplatelet medication in Japan were lower than in the USA or European countries. The adherence rate for discharge on anticoagulation for atrial fibrillation was lower than that in the USA but higher than in European countries. Such differences in adherence rates between Japan and other countries might be explained by differences in healthcare policies, guidelines, and clinical background of patients (e.g., age, race and comorbidities). From these comparisons of QIs in different countries, the current status of any country could be ascertained and efforts made to improve QIs. In the USA or Europe, the

Table 5. Association Between QI Adherence and Hospital Characteristics

| QI no. | OR* (95% CI) | P value |
|--------|--------------|---------|
| PSC8   | 1.19 (1.10–1.29) | <0.001  |
| PSC9   | 1.20 (1.07–1.34) | 0.002   |
| PSC10  | 1.19 (1.01–1.40) | 0.038   |
| PSC12  | 0.93 (0.82–1.06) | 0.295   |
| CSC12  | 1.15 (0.71–1.88) | 0.573   |

| Hospital characteristics | OR* (95% CI) | P value |
|-------------------------|--------------|---------|
| No. of stroke discharges (≥301) | | |
| PSC8 | 1.00 (0.92–1.10) | 0.916   |
| PSC9 | 0.88 (0.78–1.00) | 0.042   |
| PSC10 | 1.05 (0.87–1.27) | 0.594   |
| PSC12 | 0.94 (0.82–1.08) | 0.373   |
| CSC12 | 0.96 (0.55–1.64) | 0.868   |
| No. of beds (≥300) | | |
| PSC8 | 0.84 (0.74–0.94) | 0.003   |
| PSC9 | 0.86 (0.73–1.01) | 0.064   |
| PSC10 | 1.27 (0.99–1.62) | 0.056   |
| PSC12 | 1.33 (1.11–1.59) | 0.002   |
| CSC12 | 0.82 (0.45–1.48) | 0.504   |
| Hospital type (academic) | | |
| PSC8 | 0.98 (0.92–1.04) | 0.574   |
| PSC9 | 0.86 (0.73–1.01) | 0.064   |
| PSC10 | 1.05 (0.87–1.27) | 0.594   |
| PSC12 | 0.94 (0.82–1.08) | 0.373   |
| CSC12 | 0.96 (0.55–1.64) | 0.868   |

*ORs of adhering to each QIs (PSC8, 9, 10, 12) or occurrence of complications (CSC12) for hospital characteristics. CI, confidence interval; OR, odds ratio; QI, quality indicator.
trends of adherence rates for QIs are increasing through publication of measured QIs for stroke care. These data suggest urgent need for nationwide initiatives of quality improvement of acute stroke care in Japan.

**Structural Factors That Influence QI Adherence Rates**

Structural factors, such as hospital characteristics, are important for the improvement of the quality of stroke care. Our findings suggested that the characteristics of hospitals that are specialized for stroke care, such as higher numbers of annual stroke discharges and comprehensive stroke care capabilities, may influence the adherence rates for stroke QIs. This is in line with several previous studies regarding the association between structural and performance measures in stroke and cardiovascular diseases. For example, Bray et al reported that in hospitals with higher volumes of thrombolysis activity, there are shorter delays in administering tPA to patients after arrival to the hospital.27 In the field of cardiovascular disease, it was reported that higher hospital acute myocardial infarction (AMI) volume correlates with better adherence to process of care measures.28

On the other hand, the relationship between structural and outcome measures remains uncertain in the field of stroke and cardiovascular diseases. We previously reported the association between comprehensive stroke care capability (structural factors) and reduced in-hospital mortality in patients with all types of stroke.29 It was also reported that higher hospital volume was associated with lower mortality for stroke in Japan.30 In contrast, there was no association between AMI volume and in-hospital mortality after adjusting for patient and hospital characteristics. Further study is required to clarify the impact of improving QIs related to structural and performance factors on improvement of stroke outcomes.

**Study Limitations**

One of the major limitations of using the DPC data is the lack of data about time (onset, arrival or imaging), the National Institutes of Health Stroke Scale (NIHSS) score, or blood test values, so only 6 of the 29 developed QIs were able to be calculated in this feasibility study. Second, we cannot exclude the possibility that the same patients may be counted twice or more in this DPC database if they are readmitted or transferred to another hospital. Third, a validation study of adherence rates for individual QIs may be required, such as prescription of drugs, especially when length of hospital stay is short. Fourth, the association between performance of the process measures and outcomes remains uncertain.30 Further study is required to assess this relationship. Fifth, no specific training or instructions were provided for data entry in this study. To further improve the accuracy of the DPC data generated in routine clinical practice for research purposes, specific regular training may be required for the participating hospitals in this study.

**Future Directions**

Previous studies have specified QIs at multiple levels, recognizing that the capacity to collect data varies between health systems and settings.14 With the urgent need for a nationwide collection of data for the developed QIs, especially related to CSCs, we recently proceeded to the next stage of this initiative to develop a software program to add critical patient data, specifically required for this purpose, such as time metrics on the preset DPC data at the participating hospitals, and to automatically calculate the QI adherence rates. This next stage should further contribute to nationwide improvement in the quality of acute stroke care in Japan.

Recently, the usefulness of composite performance measures attracted increasing attention for reporting on the quality of stroke care.31 A composite performance measure is the combination of 2 or more indicators into a single number to summarize multiple dimensions of provider performance and to facilitate comparisons. Because the number of developed QIs in the CTGS initiative is high, composite performance measures may reduce the information burden by distilling the available indicators into a simple summary. To develop composite performance measure, the weights of each QIs should be assessed by their clinical importance or relationship with the outcome.

**Conclusions**

The CTGS initiative in the J-ASPECT study represents the first nationwide quality improvement initiative for acute stroke care in Japan. Despite the limited information available and the need to validate the calculated QIs, the DPC database may contribute to efficient data collection at low cost and decreased administrative burden of evaluating the developed QIs. No substantial improvement of the measured QIs before implementation of this initiative, however, suggests urgent need for nationwide quality improvement initiatives for stroke care in Japan.

**Acknowledgments**

We thank the J-ASPECT study collaborators as contributors for data collection (Supplementary Table 3). We also thank Drs. Manabu Hasegawa, Tomaatsu Tsuji, and Yasuhiro Nishijima for their helpful discussions, Professors Takamasa Kayama, Nobuo Hashimoto and Hajime Arai for their supervision of the collaboration with the Japan Neurosurgical Society, Professors Norhiro Suzuki, Yoichiro Hashimoto, Teiji Tominaga, Michiyasu Suzuki, Yasuhiro Hasegawa, Nobuyuki Sakai and Susumu Miyamoto for supervision of the collaboration with the Japan Stroke Society. We also thank Drs. Fumiaki Nakamura, Manabu Hasegawa, Yasuhiro Nishijima, Akiko Ishigami, and Naotsugu Iwakami for their helpful discussions, and Ms. Arisa Ishitoko for her secretarial assistance.

**Disclosures**

Dr. K. Nishimura reports honoraria from Philips Japan Co., Terumo Co. Dr. Kada reports membership of independent data monitoring committees of clinical trials taken by Bayer Yakuhin Ltd., outside the submitted work. Dr. Ogasawara reports consigned research funding from the Nihon Medi-Physics Co., Ltd. Dr. Hashimoto reports speaker fees from Bristol-Myers Squibb, Byer Yakuhin, Daiichi-Sankyo and Pfizer. Dr. Hirano reports lecture fees and honoraria from Bristol-Myers Squibb, Byer Yakuhin, Daiichi-Sankyo, Nippon Boehringer Ingelheim, and Sanofi. Dr. Hoshino reports honoraria from Nippon Boehringer-Ingelheim Co., Ltd., Bayer Yakuhin Ltd., Daiichi-Sankyo Co., Ltd., Pfizer Inc. and Bristol-Myers Squibb Company Co., Ltd. Ryo Itabashi received honoraria for oral presentations from Bayer, Bristol-Myers Squibb, Takeda, Tanabe-Mitsubishi Parma, Daiichi-Sankyo, Boehringer-Ingelheim, Kowa Pharmaceutical Company, Otsuka Pharmaceutical, Sanofi, Pfizer, Stryker and Johnson and Johnson, and received research support not attributed in the manuscript from Tohoku Fukushi University. Dr. Matsumura reports honoraria from Medtronic Japan, Stryker Japan, Terumo, Johnson & Johnson Japan, Medics Hirata and Century Medical. Dr. Sasaki reports honoraria from Mitsubishi Tanabe Pharma Co., Actelion Pharmaceuticals, Eisai Co., Nihon Medi-Physics Co., Dai-ichi Sankyo, Bayer Healthcare, Otsuka Pharmaceutical, Boehringer-Ingelheim, Fujifilm Pharmaceuticals, Chugai Pharmaceutical Co., Ltd., and Hitachi Ltd. Dr. Takewaki reports honoraria from Dai-ichi Sankyo, Otsuka Pharmaceutical, Pfizer, speaker fees.
from Dai-iichi Sankyo, Bayer Healthcare, Otsuka Pharmaceutical, Pfizer, Bristol-Myers Squibb, Boehringer-Ingelheim, and Takeda Pharmaceutical.

Heuschmann PU, Biegler MK, Busse O, Elsner S, Grau A, Hasenbein U, et al. Development and implementation of evidence-based indicators for measuring quality of acute stroke care: The Quality Indicator Board of the German Stroke Registers Study Group (ADSR). Stroke 2006; 37: 2573–2578.

Ashland K, Hulte Asberg K, Norrving B, Stegmayr B, Tenent A, Wester PO. Riks-stroke: A Swedish national quality register for stroke care. Cerebrovasc Dis 2003; 15(Suppl 1): 5–7.

Mainz J, Krog BR, Bjornshave B, Bartels P. Nationwide continuous quality improvement using clinical indicators: The Danish National Indicator Project. Int J Qual Health Care 2004; 16(Suppl 1): i45–i50.

Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR, Lazaro P, et al. The RAND/UCLA appropriateness method user's manual. Santa Monica, CA: RAND Corporation, 2001.

The Japan Stroke Society. Japanese guidelines for the management of stroke 2015. Kyowa kikaku, 2015.

Leifer D, Bravata DM, Conners JJ 3rd, Hinchey JA, Jauch EC, Johnston SC, et al. Metrics for measuring quality of care in comprehensive stroke centers: Detailed follow-up to Brain Attack Coalition comprehensive stroke center recommendations. A statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke 2011; 42: 849–877.

Powers WJ, Derdeyn CP, Biller Soffey CS, Hoh BL, Jauch EC, Johnston KC, et al. 2015 American Heart Association/American Stroke Association focused update of the 2013 guidelines for the early management of patients with acute ischemic stroke regarding endovascular treatment: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke 2015; 46: 3020–3035.

Diabetes Mellitus managed by the Japan Agency for Medical Research and Development, Grants-in-Aid from the Japanese Ministry of Health, Labour and Welfare. The funding sources had no role in the study design, data collection and analysis, manuscript preparation, or decision to publish.

Sources of Funding

This work was supported by the Practical Research Project for Lifestyle-related Diseases including Cardiovascular Diseases and Diabetes Mellitus managed by the Japanese Agency for Medical Research and Development, Grants-in-Aid from the Japanese Ministry of Health, Labour and Welfare. The funding sources had no role in the study design, data collection and analysis, manuscript preparation, or decision to publish.

References

1. Measuring and improving quality of care: A report from the American Heart Association/American College of Cardiology First Scientific Forum on Assessment of Healthcare Quality in Cardiovascular Disease and Stroke. Circulation 2000; 101: 1483–1493.

2. Alberts MJ, Hademenos G, Latchaw RE, Jagoda A, Marler JR, Mayberg MR, et al. Recommendations for the establishment of primary stroke centers: Brain Attack Coalition. JAMA 2000; 283: 3102–3109.

3. Alberts MJ, Latchaw RE, Selman WR, Shepher T, Hadley MN, Brass LM, et al. Recommendations for comprehensive stroke centers: A consensus statement from the Brain Attack Coalition. Stroke 2005; 36: 1597–1616.

4. Adams R, Acker J, Alberts M, Andrews L, Atkinson R, Fenelon K, et al. Recommendations for improving the quality of care through stroke centers and systems: An examination of stroke center identification options: Multidisciplinary consensus recommendations from the Advisory Working Group on Stroke Center Identification Options of the American Stroke Association. Stroke 2002; 33: e1–e7.

5. Comprehensive Stroke Certification: Standardized Performance Measures. http://www.jointcommission.org/performance_measures_for_comprehensive_stroke_centers/ (accessed October 31, 2018).

6. Schwanh LH, Fonarow GC, Reeves MJ, Pan W, Frankel MR, Smith EE, et al. Get With the Guidelines – Stroke is associated with sustained improvement in care for patients hospitalized with acute stroke or transient ischemic attack. Circulation 2009; 119: 107–115.

7. Lindsay P, Bayley M, McDonald A, Graham ID, Warner G, Phillips S. Toward a more effective approach to stroke: Canadian best practice recommendations for stroke care. Can Med Assoc J 2008; 179: 1418–1425.

8. Rudd AG, Pearson M. National stroke audit. Clin Med (Lond) 2002; 2: 496–498.

9. Heuschmann PU, Biegler MK, Busse O, Elsner S, Grau A, Hasenbein U, et al. Development and implementation of evidence-based indicators for measuring quality of acute stroke care: The Quality Indicator Board of the German Stroke Registers Study Group (ADSR). Stroke 2006; 37: 2573–2578.

10. Ashland K, Hulte Asberg K, Norrving B, Stegmayr B, Tenent A, Wester PO. Riks-stroke: A Swedish national quality register for stroke care. Cerebrovasc Dis 2003; 15(Suppl 1): 5–7.

11. Mainz J, Krog BR, Bjornshave B, Bartels P. Nationwide continuous quality improvement using clinical indicators: The Danish National Indicator Project. Int J Qual Health Care 2004; 16(Suppl 1): i45–i50.

12. Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR, Lazaro P, et al. The RAND/UCLA appropriateness method user's manual. Santa Monica, CA: RAND Corporation, 2001.

13. The Japan Stroke Society. Japanese guidelines for the management of stroke 2015. Kyowa kikaku, 2015.

14. Leifer D, Bravata DM, Conners JJ 3rd, Hinchey JA, Jauch EC, Johnston SC, et al. Metrics for measuring quality of care in comprehensive stroke centers: Detailed follow-up to Brain Attack Coalition comprehensive stroke center recommendations. A statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke 2011; 42: 849–877.

15. Powers WJ, Derdeyn CP, Biller Soffey CS, Hoh BL, Jauch EC, Johnston KC, et al. 2015 American Heart Association/American Stroke Association focused update of the 2013 guidelines for the early management of patients with acute ischemic stroke regarding endovascular treatment: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke 2015; 46: 3020–3035.

16. Iihara K, Nishimura K, Kada A, Nakagawa J, Ogasawara K, Ono J, et al. Effect of the use of ambulance-based thrombolysis volume and speed of thrombolysis administration in in-hospital mortality of patients with ischemic and hemorrhagic stroke: J-ASPECT study. PLoS One 2014; 9: e96819.

17. Suzuki S, Yasunaga H, Matsu H, Fushimi K, Saito Y, Yamashita T. Cerebral infarction after intraarterial and intravenous chemoradiotherapy for head and neck cancer: A retrospective analysis using a Japanese inpatient database. Head Neck 2016; 38: 1354–1358.

18. Yamana H, Moriwaki M, Horiguchi H, Kodan M, Fushimi K, Yasunaga H. Validity of diagnoses, procedures, and laboratory data in Japanese administrative data. J Epidemiol 2017; 27: 476–482.

19. Yasuda S, Nakao K, Nishimura K, Miyamoto Y, Sumita Y, Shishido T, et al. The current status of cardiovascular medicine in Japan: Analysis of a large number of health records from a nationwide claim-based database, JROAD-DPC. Circ J 2016; 80: 2327–2335.

20. Kurogi R, Kada A, Nishimura K, Kamitani S, Nishimura A, Sayama T, et al. Effect of treatment modality on in-hospital outcome in patients with subarachnoid hemorrhage: A nationwide study in Japan (J-ASMR) Stroke Study. J Neurol 2017; 1: 9.

21. Fonarow GC, Smith EE, Saver JL, Reeves MJ, Hernandez AF, Peterson ED, et al. Improving door-to-needle times in acute ischemic stroke: The design and rationale for the American Heart Association/American Stroke Association’s Target: Stroke initiative. Stroke 2011; 42: 2983–2989.

22. Ebiner M, Winter B, Wendt M, Weber JE, Waldschmidt C, Rozanski M, et al. Effect of the use of ambulance-based thrombolysis on time to thrombolysis in acute ischemic stroke: A randomized clinical trial. JAMA 2014; 311: 1622–1631.

23. Schwanh LH, Reeves MJ, Frankel M. Designing a sustainable national registry for stroke quality improvement. Am J Prev Med 2006; 31: S251–S257.

24. The Joint Commission 2016 Annual Report. http://jointcommis-sion.new-media-release.com/2016_annual_report/#nationalper forance (accessed September 25, 2017).

25. Hillmann S, Wiedmann S, Fraser A, Baeza J, Rudd A, Norrving B, et al. Temporal changes in the quality of acute stroke care in five national audits across Europe. Bionet Res Int 2015; 2015: 432497.

26. Busse O, Campbell J, Cloud GC, Hoffman A, Tyrrell PJ, Wolfe CD, et al. Bigger, faster?: Associations between hospital thrombolysis volume and speed of thrombolysis administration in acute ischemic stroke. Stroke 2013; 44: 3129–3135.

27. Harrison RW, Simon D, Miller AL, de Lemos JA, Peterson ED, Wang TY. Association of hospital myocardial infarction volume with American College of Cardiology/American Heart Association performance measures: Insights from the
National Cardiovascular Data Registry. *Am Heart J* 2016; **178**:95–101.

29. Tsugawa Y, Kumamaru H, Yasunaga H, Hashimoto H, Horiguchi H, Ayanian JZ. The association of hospital volume with mortality and costs of care for stroke in Japan. *Med Care* 2013; **51**:782–788.

30. Bray BD, Ayis S, Campbell J, Hoffman A, Roughton M, Tyrrell PJ, et al. Associations between the organisation of stroke services, process of care, and mortality in England: Prospective cohort study. *BMJ* 2013; **346**:f2827.

31. Peterson ED, Delong ER, Masoudi FA, O’Brien SM, Peterson PN, Rumsfeld JS, et al. ACCF/AHA 2010 position statement on composite measures for healthcare performance assessment: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures (Writing Committee to develop a position statement on composite measures). *Circulation* 2010; **121**:1780–1791.

**Supplementary Files**

Please find supplementary file(s);
http://dx.doi.org/10.1253/circj.CJ-19-0089