

Quality Management Program of Stroke Rehabilitation Using Adherence to Guidelines: A Nationwide Initiative in Japan

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Background and Aim: In recent years, interest in the quality of medical care has rapidly increased worldwide. However, quality indicators that contribute to establishing standard treatment in stroke medicine, especially rehabilitation, are not well-developed in Japan. Japan has established Kaifukuki (convalescent) rehabilitation wards, and the development of quality indicators for stroke rehabilitation in the convalescent phase is an urgent issue. *Methods:* We first reviewed the literature regarding quality indicators for stroke rehabilitation. Next, we extracted candidate indicators from identified reports and guidelines and surveyed educational hospitals certified by the Japanese Association of Rehabilitation Medicine. On the basis of the survey results, we reevaluated the suitability of the proposed indicators in discussions with an expert panel. *Results:* The questionnaire survey highlighted several important items that revealed there is room for improvement in adherence. For stroke rehabilitation in the convalescent phase, we adopted 15 indicators that were feasible as indicators to be used for comparisons between facilities, based on scoring by and opinions of the expert panel. These indicators measured structure (2 indicators), process (5 indicators), and outcome (8 indicators). *Conclusion:* This is the first study to establish quality indicators to standardize stroke rehabilitation in Japan. We developed this set of 15 indicators using an evidence-based approach. However, many tasks remain for continuous quality improvement.

Key Words: Stroke Rehabilitation—quality indicator—healthcare—evidence-based practice

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Received March 19, 2019; revision received June 2, 2019; accepted June 22, 2019.

Financial Disclosures: Dr. Matsumoto reports grant support from Teijin Pharma Limited. Dr. Kitazono reports speaker fees from Bayer Yakuin Ltd. and Daiichi Sankyo Co. Ltd., consulting fees from Chugai Pharmaceutical Co. Ltd., and grant support from Takeda Pharmaceutical Co. Ltd., Daiichi Sankyo Ltd., Mitsubishi Tanabe Pharma Co., Eisai Co. Ltd., Astellas Pharma Inc., Chugai Pharmaceutical Co. Ltd., and MSD KK. Dr. Iihara reports grant support from AstraZeneca, Otsuka Pharmaceutical, Nihon Medi-Physics Co. Dr. Shimodozono reports lecture fee from Eli Lilly Japan K.K., and consulting fees from Yaskawa Electric Co. The remaining authors report no conflicts of interest.

Funding: This work was supported by the Practical Research Project for Life-style related Diseases including Cardiovascular Diseases and Diabetes Mellitus managed by the Japan Agency for Medical Research and Development (AMED) (16k0210046h0002; Principal Investigator: K.I., Co-Investigator: M.S.). The funder had no role in the study design, data collection and analysis, manuscript preparation, or decision to publish.

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1052-3057/\$ - see front matter

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<https://doi.org/10.1016/j.jstrokecerebrovasdis.2019.06.028>

Background

Stroke is the second leading cause of death and disability worldwide.^{1,2} In Japan, stroke is the third leading cause of death³ and the second leading cause of long-term disability, including being bedridden.⁴ Recently, the quality of medical care has received increasing attention worldwide. In the United States, several health care organizations and entities have undertaken initiatives related to measuring and improving the quality of care provided for patients with acute stroke, to certify primary and comprehensive stroke centers.⁵⁻⁸ However, Japan has not implemented nationwide efforts for quality management of stroke care and certification of stroke centers. Development of quality indicators (particularly in rehabilitative care) has not progressed.

A characteristic element of the stroke rehabilitation system in Japan is interdisciplinary postacute rehabilitation units. These are called Kaifukuki (convalescent) rehabilitation wards (KRWs), which were incorporated into the Japanese medical insurance system in 2000.⁹ The Japan Ministry of Health, Labour, and Welfare define KRWs as the main system of inpatient rehabilitation facilities covered by the medical insurance system. Patients eligible for the KRW are those with disabilities that are mainly owing to neurological disorders (including stroke) or orthopedic diseases, such as hip fractures. The number of KRW beds in Japan has continuously increased; there were 4019 beds in 2000, 30,499 in 2005, 60,206 in 2010, and 77,102 in 2015. This means that there are over 60 beds per 100,000 population, comprising 4.6% of the total hospital beds in the country. KRWs can provide extended coverage of inpatient rehabilitation up to 180 days after stroke, and 3 hours per day of rehabilitation (including physical, occupational, and speech therapy). There are no similar inpatient rehabilitation systems elsewhere in the world in terms of length of stay (LOS) and intensity of rehabilitative interventions, including in developed countries such as in North America and Europe.

The number of hospitals in Japan equipped with KRWs has increased, and quality management in KRWs is now necessary. Since 2017, assessment of a functional independence measure (FIM)¹⁰ performance index has been performed as a quality indicator. For further quality assurance, structure, or process indicators should be investigated, in addition to outcome measures. There is evidence for the efficacy of postacute rehabilitation in reducing the mortality and dependence of patients with stroke.¹¹⁻¹³ Improved adherence to published rehabilitation guidelines has been linked to significantly improved functional outcomes.^{14,15} This study aimed to investigate adherence to guidelines and to develop indicators in the convalescent phase, so as to promote the uniformization of standard treatments that are compatible with Japanese medical conditions and international perspectives, while remaining cognizant that the KRW is a system unique to Japan.

Methods

Dimensions of Quality and Components of Stroke Rehabilitation

Three facets of health care must be considered, to effectively measure the quality of rehabilitation services: structure, process, and outcomes. These 3 components have been called the “Donabedian triad”.¹⁶ Structure represents systemic organization, human resources (including staff knowledge and experience), and technology. Process describes factors such as compliance with guidelines and evaluation protocols. Outcome measures evaluate changes in a patient’s condition after an intervention as compared with before the intervention.¹⁴

Methodological Requirements for Quality Indicators

Quality indicators should be based on the best scientific evidence available, and the outcomes measured should be meaningful for the patient and society. Measures should be reliable and should allow for case-mix adjustment of participating institutions, to ensure that observed differences are related to performance rather than disparities in patient characteristics. Furthermore, measures should be sensitive to changes in medical care, to encourage health care providers to improve their services. It should be feasible for staff members at participating facilities to collect data, and the effort required for data collection should be kept at a minimal level.⁵ In addition, indicators are not universal but should change based on the current medical environment and latest evidence.

Methodological Approach

First, we extracted candidate indicators from the reviewed literature and guidelines. As we predicted a small number of published studies on indicator development, particularly in the convalescent phase, we searched and extracted candidate indicators for stroke rehabilitation broadly, without focusing on any 1 of the 3 phases: acute, convalescent, and chronic phase. Second, we conducted a questionnaire survey targeting educational hospitals certified by the Japanese Association of Rehabilitation Medicine (JARM). Then, on the basis of the survey results, we examined and re-evaluated the candidate indicators and obtained an evaluation from an external expert panel, to determine a set of indicators. The expert panel evaluated the adequacy of indicators for each of the 3 phases. The ultimate goal of this report is the development of quality indicators for stroke rehabilitation in the convalescent phase.

Literature Review

To extract potential indicators, we performed a literature search in PubMed and the Cochrane Database of Systematic Reviews. We also used recommendations from

additional records identified through other sources, including the chapter on rehabilitation in the Japanese guideline for stroke care,¹⁷ to supplement the small number of previous studies on indicator development.

Questionnaire Survey on Adherence to Guidelines for Rehabilitation Facilities

The questionnaire survey was entitled “Questionnaire on the quality indicators for stroke rehabilitation contributing to the establishment of standard medical care,” and it was conducted online from March 14 to June 14, 2016. Respondents were representative supervisors from educational hospitals certified by the JARM. The questionnaire comprised 39 items: 7 questions about hospital attributes and 32 questions about quality indicators. We asked whether respondents’ facilities had a structure indicator, were implementing process indicators, and whether they thought outcome measures were appropriate (ie, whether or not they measured outcomes).

Funding and Ethics Statement

This study was conducted as part of the “Development of Evaluation Indicators for Control of Cardiovascular Disease Including Stroke” study conducted by the Japan Agency for Medical Research and Development. The questionnaire survey was approved by the Research Ethics Review Board of the JARM on February 29, 2016.

Expert Panel

The expert panel comprised experts in the field of stroke and rehabilitation. These experts were from various university and city hospitals from across Japan. All experts were on the Board of the Japan Stroke Society and/or JARM. On the basis of the results of the questionnaire survey, we selected indicators that demonstrated room for improvement despite their importance, and those where improvement in adherence was thought to contribute to patient outcomes. The expert panel evaluated these items using a 9-point Likert scale. We compiled the results, and selected indicators with a median score of more than equal to 7 that did not have large inconsistencies in the experts’ scores.

Results

A detailed timetable of the study process is presented in Supplementary Table 1. In the literature search, 131 potentially relevant articles were screened according to the titles and abstracts, and 36 articles were extracted (Supplementary Fig. 1). However, we found that few documents were available on the development of quality indicators for stroke rehabilitation. Grube et al reported the development of evidence-based quality indicators for stroke rehabilitation according to a systematic literature review, rating of published evidence, an external peer review, and

evaluation in a pilot study before implementation.¹⁸ Those authors adopted a final set of 18 indicators that measured processes (9 indicators), outcomes (5 indicators), and structures (4 indicators). To supplement the inadequacy in the literature search, we additionally examined 8 records, including guidelines. Major regulatory organizations in the United States, such as the Commission on Accreditation of Rehabilitation Facilities, also publish indicators that measure the quality of medical rehabilitation.¹⁹ In addition, we referred to existing quality indicators from other countries.²⁰⁻²⁴ However, most of these reports did not comprise indicators that included specific rehabilitation processes that are specialized for stroke rehabilitation. Considering the medical environment for stroke rehabilitation (including KRWs) in Japan, we thought it necessary to include recommended items with evidence grade B or higher in the Japanese Guidelines for the Management of Stroke 2015¹⁷ as candidate indicators. As a result, we selected 19 articles including candidate indicators.

On the basis of information from these sources, we extracted 92 candidate indicators from 19 articles and proposed an additional 5 candidate indicators; a total of 97 candidates were selected (structure, 8 candidates; process, 77 candidates; outcome, 12 candidates). We initially selected 26 candidates from 18 items of Grube et al,¹⁸ and 72 candidates from the Japanese Guidelines for the Management of Stroke 2015.¹⁷ The remaining 17 articles contributed to establishing 28 candidates (Supplementary Table 2). Then, we conducted a questionnaire survey of representative supervisors from educational hospitals certified by the JARM. We received responses from 195 facilities, which accounted for 32% of the 618 facilities from which we requested responses. In total, 40% of responses concerned private hospitals, 33% public hospitals, and 27% involved university hospitals. In addition, 36% of participating facilities had 0-200 beds, 26% had 201-400 beds, 13% had 401-600 beds, 13% had 601-800 beds, and 12% had 801 or more beds. The responses showed that 51% of participating facilities had acute wards, 49% had KRWs, and 19% had chronic wards.

Supplementary Table 2 also presents results from the survey for each of the 97 candidates. There were few facilities with structure indicators for smoking cessation treatment and family education programs (48% and 47%, respectively), suggesting that there is room for improvement in these indicators. As a process indicator, 76% of hospitals conducted evaluations based on the International Classification of Functioning, Disability and Health. Ankle-foot orthosis was used in rehabilitation for gait disturbance in all facilities. However, only 47% of facilities used functional electrical stimulation (FES) for gait rehabilitation; this was expected to be feasible and improve patient outcomes in more facilities.

Concerning upper limb function, the implementation rate of constraint-induced movement therapy^{25,26}

(recommended as grade A in the Japanese guideline) was 35%. However, the feasibility of constraint-induced movement therapy in the Japanese medical system is low because this treatment method requires 6 hours of training per day, and the number of patients for which it is applicable is limited. The mutual superiority of other specific training for upper limb function (reaching movement,²⁷ task-oriented training,²⁸ repetitive exercise of both upper limbs,²⁹ repetitive facilitative exercise,³⁰ and mirror therapy³¹) were unclear. Therefore, we considered that implementation of neuromuscular electrical stimulation (NMES) for affected upper limbs^{32,33} (recommended as grade B in the Japanese guideline) was an appropriate candidate indicator; NMES was conducted by 58% of facilities. For dysphagia, many facilities carried out evaluation by speech and language therapists (94%), videofluoroscopic examination (91%), or comprehensive intervention by multi-occupation (85%), although videoendoscopic examination was not adequately practiced (67%).

In terms of outcome measures, many responses regarding indicators for movement and walking reported use of the 10-meter walk test and Timed Up & Go test,³⁴ as appropriate (83% and 76%, respectively). As an outcome measure for overall rehabilitation, most representatives indicated that FIM, home discharge rate, patient satisfaction, care burden, and LOS were appropriate.

Figure 1 shows a flow diagram for the selection process of the quality indicators for the convalescent phase. On

the premise of the methodological requirements for quality indicators mentioned in the Methods section of the present paper, we shared these questionnaire results with the expert panel and identified 14 important items that had insufficient adherence despite a highly recommended grade, or that had consensus for suitability as an outcome indicator. We developed a presentation for each indicator and clarified the method of calculation and measurement using objective numerical values (Supplementary Table 3). Then, the suitability of each item as a quality indicator was evaluated for each of the acute, convalescent, and chronic phases by the panel, using a 9-point Likert scale (1 = definitely inappropriate to 9 = definitely applicable). As a result of the evaluation regarding the convalescent phase, application of FES for gait disturbance as a process indicator and LOS as an outcome indicator were withdrawn, based on low scoring. The reasons for the low scoring of these candidate indicators was that FES devices are not yet popular in Japan, and LOS tends to depend on regional characteristics of community resources (eg, urban versus rural) rather than each hospital. The expert panel discussed adding physical therapy aimed at increasing the amount of walking for patients with gait disturbance, and occupational therapy aiming to increase the use of affected upper limbs for patients with mild upper limb dysfunction. However, these items were eventually dismissed based on measurement uncertainty. Instead, we added the time of physical therapy and occupational

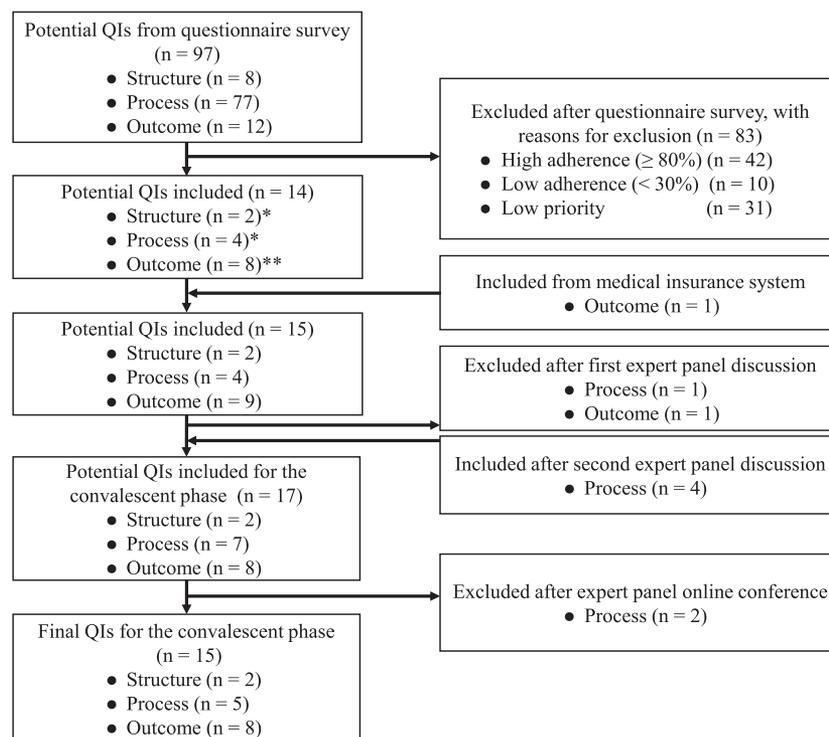


Figure 1. Flow diagram for the selection process of quality indicators (QIs) for stroke rehabilitation in the convalescent phase. *Inclusion criteria: with adherence (30%-79%) and high priority. **Inclusion criteria: with consensus for suitability (50% or more).

therapy as an indicator that can be reliably measured using “medical receipts,” that is, statements of the medical fee that the hospital charges the insurer for the medical treatment which the patient received. As a result, 15 indicators remained for stroke rehabilitation in the convalescent phase (Table 1).

Discussion

This is the first study focused on improving the quality of stroke rehabilitation in Japan, where KRWs have been

implemented as a system for providing inpatient rehabilitation for patients poststroke. We extracted candidate indicators from previous research and guidelines and conducted a questionnaire survey of certified training facilities. Many items showed insufficient adherence, even among those with a high recommended grade. This highlights the importance of this study in improving the quality of medical care.

The study by Grube et al that developed quality indicators for stroke rehabilitation adopted 18 indicators.¹⁸ In our study, most of the indicators from that study were

Table 1. Development of quality indicators for stroke rehabilitation in the convalescent phase

| Potential indicators | Survey responses (%) | Inclusion | Reevaluation by expert panel | Final indicators after expert panel discussion |
|---|----------------------------------|-----------|------------------------------|--|
| Structure | Adherence | | | |
| Smoking cessation programs including non-smoking education | 48 | + | + | + |
| Family education program (family involved in education) | 47 | + | + | + |
| Process | Adherence | | | |
| Evaluation based on ICF concept | 76 | + | + | + |
| Functional electrical stimulation for patients with gait disturbance | 47 | + | – | |
| Physical therapy time for patients with gait disturbance | *N/A | | + | + |
| Physical therapy aimed at increasing the amount of walking of patients with gait disturbance | *N/A | | + | – |
| Use of electrical stimulation for patients with upper limb dysfunction | 58 | + | + | + |
| Occupational therapy time for patients with upper limb dysfunction | *N/A | | + | + |
| Occupational therapy aiming to increase the use of affected upper limb in patients with mild upper limb dysfunction | *N/A | | + | – |
| Videoendoscopic examination for patients with dysphagia | 67 | + | + | + |
| Outcome | Consensus for suitability | | | |
| 10-meter walk test | 83 | + | + | + |
| Timed Up & Go test | 76 | + | + | + |
| Home discharge rate | 78 | + | + | + |
| Patient satisfaction | 63 | + | + | + |
| Care burden | 56 | + | + | + |
| Length of stay | 52 | + | – | |
| Gain of functional independence measure | 82 | + | + | + |
| Efficiency of functional independence measure | 72 | + | + | + |
| Performance index of functional independence measure | *N/A | + | + | + |

Abbreviations: ICF, International Classification of Functioning, Disability and Health.

*N/A: not applicable.

rejected because of high adherence reported in the questionnaire survey, except for smoking cessation and family education programs. In contrast, screening of depression was rejected as adherence was too low in our survey (17%). This may be an indicator for further improvement, after improvement of indicators according to identification of high-priority indicators requiring improvement. The difference between the indicators identified by Grube et al and our study may suggest that the specific content or nature of rehabilitation is currently more relevant in Japan than risk management or screening for complications. In fact, a FIM performance index has been adopted as an outcome indicator in the medical insurance system since 2017, and appropriate processes and equipping structures should be implemented to achieve the FIM performance index. NMES for upper limb function and videoendoscopic examination for dysphasia are good examples from the present indicators. The American Heart Association guideline published in 2016 (after data for the present study had been collected) suggests that it is reasonable to consider NMES for individuals with minimal volitional movement within the first few months after stroke (recommended as class IIa).³⁵ In our survey, the implementation rates of both indicators showed room for improvement (58% and 67%, respectively), so we adopted these indicators. However, although the implementation rate of FES for gait disturbance (which is also recommended by the guidelines^{17,35}) was not sufficient, it was not accepted as an indicator by the expert panel because of the unpopularity of FES devices. Training time for physical and occupational therapy was adopted as an indicator because the actual training time provided had not yet reached the maximum time approved by the medical insurance system.

This study had several limitations. First, we conducted a literature search using only 2 databases and did not exhaustively search other databases, such as CENTRAL, EMBASE, PEDro, and OTSeeker. Accordingly, relevant published articles or proposed candidate indicators might have been missed. Second, the questionnaire response rate was relatively low (32%). Further, it might be inferred that the answers obtained were responses from elite facilities because our survey targeted educational hospitals certified by the JARM. As teaching hospitals, these hospitals have 1 or more board-certified physiatrists, and it is known that clinical management by board-certified physiatrists is associated with good functional improvement in KRWs.³⁶ In addition, physicians practicing in KRWs are often specialized in neurosurgery, internal medicine (neurology), or orthopedic surgery and often attend inpatients of their own specialty. Therefore, respondents to our questionnaire from these facilities might be more familiar with stroke rehabilitation than those from other facilities. This suggests that quality assurance might be poorer in noneducational hospitals. Third, regarding the selection of candidate indicators, there was a specific limitation in the

field of rehabilitation, namely, uncertainty of measurement. There were few items that could be extracted from medical receipts, and it was difficult to measure the content or nature of the treatment because a rehabilitative treatment was provided by a person (therapist). Some literature has reported that monitoring and reporting of nondrug interventions (including stroke rehabilitation) tends to be incomplete.³⁷ As the resolution of these problems is important to ensure reliability of clinical research, several recommendations have been made.³⁸ In clinical practice, advanced robotics, wearable devices, or artificial intelligence may help to address these problems.³⁹ Fourth, there was no existing database that could operate virtually and verify quality indicators.

Because rehabilitation medicine has progressed rapidly, we would like to build a system in cooperation with academic societies that can continuously improve care quality. In addition, increasing the number of board-certificated physiatrists and enriching the education of therapists may be important for improving the quality of stroke rehabilitation.

Conclusions

Herein, we reported the development of a set of quality indicators for stroke rehabilitation in the convalescent phase, with the aim of standardization in Japan, where KRWs are established. This study may contribute to national policy research, and countermeasures for quality improvement in medical insurance may be developed based on these results. It will be necessary to build a nationwide database to continuously improve quality and adjust indicators in future study.

Acknowledgment

We wish to thank Drs. Toshiyuki Fujiwara, Kozo Hanayama, Setsuro Ibayashi, Katsunori Ikoma, Shin-ichi Izumi, Wataru Kakuda, Ichiro Miyai, Satoru Saeki, and Shigeru Sonoda for their helpful discussions in reviewing the indicators as the expert panel. We are also grateful to the doctors who cooperated with the questionnaire survey targeting educational hospitals of the JARM. We also thank Audrey Holmes, MA, from Edanz Group (www.edanzediting.com/ac) for editing a draft of this manuscript.

Conflicts of Interest

None.

Supplementary materials

Supplementary material associated with this article can be found in the online version at [doi:10.1016/j.jstrokecerebrovasdis.2019.06.028](https://doi.org/10.1016/j.jstrokecerebrovasdis.2019.06.028).

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