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Complete List of Authors:

Shiota, Shigehito; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Hospital, Department of Rehabilitation
Kitagawa, Toshiro; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Graduate School of Biomedical and Health Sciences , Department of Cardiovascular medicine
Goto, Naoya; Hiroshima University Hospital, Department of Rehabilitation
Fujisita, Hironori; Hiroshima University Hospital, Department of Rehabilitation
Tamekuni, Yurika; Hiroshima University Hospital, Department of Rehabilitation
Nakayama, Susumu; Home nursing station Sakurazaka
Mio, Naoki; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Hospital, Department of Rehabilitation
Kanai, Kana; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Hospital, Department of Rehabilitation
Naka, Makiko; Hiroshima University Hospital, Heart Failure Center
Yamaguchi, Mizuho; Hiroshima University Hospital, Heart Failure Center
Mochizuki, Mariko; Hiroshima Care Manager Association
Ochikubo, Hiroyuki; Hiroshima Care Manager Association
Hidaka, Takayuki; Hiroshima Prefectural Hospital, Department of Cardiovascular Medicine
Yasunobu, Yuji; Miyoshi Medical Association Hospital, Department of Cardiovascular Medicine
Nakano, Yukiko; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Graduate School of Biomedical and Health Sciences, Department of Cardiovascular medicine
Kihara, Yasuki; Hiroshima University Graduate School of Biomedical and Health Sciences
Kimura, Hiroaki; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Hospital, Department of Rehabilitation Medicine

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Original research

Development and validation of an ICF-based comprehensive assessment for older patients with heart failure: the RAND/UCLA appropriateness method

Shigehito Shiota[1,2], Toshiro Kitagawa[1,3], Naoya Goto[2], Hironori Fujisita[2], Yurika Tamekuni[2], Susumu Nakayama[4], Naoki Mio[1,2], Kana Kanai[1,2], Makiko Naka[1], Mizuho Yamaguchi[1], Mariko Mochizuki[5], Hiroyuki Ochikubo[5], Takayuki Hidaka[6], Yuji Yasunobu[7], Yukiko Nakano[1,3], Yasuki Kihara [8], Hiroaki Kimura[1,9]

[1] Heart Failure Center, Hiroshima University Hospital, Hiroshima, Japan

[2] Division of Clinical Support, Department of Rehabilitation, Hiroshima University Hospital, Hiroshima, Japan

[3] Hiroshima University Graduate School of Biomedical and Health Sciences, Hiroshima, Japan

[4] Home nursing station Sakurazaka, Hiroshima, Japan

[5] Hiroshima Care Manager Association, Hiroshima, Japan.

[6] Department of Cardiovascular Medicine, Hiroshima Prefectural Hospital, Hiroshima, Japan

[7] Department of Cardiovascular Medicine, Miyoshi Medical Association Hospital, Hiroshima, Japan

[8] Hiroshima University Graduate School of Biomedical and Health Sciences, Hiroshima, Japan

[9] Department of Rehabilitation Medicine, Hiroshima University Hospital, Hiroshima, Japan

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Corresponding author:

Shigehito Shiota

Email: sshiota@hiroshima-u.ac.jp

Address: 1-2-3, Kasumi, Minami-ku, Hiroshima City, Hiroshima, Japan

ABSTRACT

Objective: Since the number of elderly patients with heart failure continues to increase, a common evaluation method for medical and nursing care needs to be established. This study aimed to examine the validity of a scoring method for older patients with heart failure based on the International Classification of Functioning, Disability and Health (ICF), which we developed through a Delphi study that was conducted by an expert panel.

Design: Cross-sectional survey. We applied the RAND/UCLA Appropriateness Method with a modified Delphi method.

Setting and participants: We included a panel of 26 multidisciplinary experts on heart failure care: five general practitioners, two cardiovascular physicians, 10 care managers, three nurses, pharmacist, two physical therapists, occupational therapist, nutritionist and social worker.

Measures: Forty-three ICF categories specific to older patients with heart failure were rated for appropriateness on a 9-point Likert scale ranging from 1 (very inappropriate) to 9 (very appropriate). The three evaluation items were as follows: (1) grading criteria, (2) evaluation methods in the supplementary grading criteria, and (3) scoring criteria based on the supplementary criteria. The median value of 7 to 9 was evaluated as "appropriate".

Results:

A total of 21 panel members responded to all Delphi rounds. The median rating for all questions in the 43 ICF categories was "7-9: appropriate. Tertile 7-9 was more than 80% (agreement) for all 42 ICF categories except d450 walking. After modifying the scoring criteria for the supplementary assessment method for d450 walking, all questions had reached a consensus.

Conclusion: We developed an ICF-based scoring method for older patients with heart failure and showed that there was a consensus of "appropriate" and "agreement" by the expert panel.

Keywords: heart failure, older people, ICF, scoring methods, RAND/UCLA Appropriateness Method

Strengths and limitations of this study

►An expert panel familiar with heart failure care, consisting of home physicians, care managers, and medical multidisciplinary professionals, rated the "appropriateness" of the questions in each ICF category through a multiple-round process to achieve a consensus.

► The assessment domains studied the 43-item ICF relevant to older adults with heart

failure, covering not only the medical assessment but also the physical and mental functioning, activity and social participation, and environmental factors.

►The expert panel comprised general practitioners, cardiologists, and paramedical professions (rehabilitation, nursing care, and welfare), but caution is needed in generalizing the findings because of the study's limited geographical area.

INTRODUCTION

In Japan, cardiovascular disease is the second leading cause of death. [1] In addition, cardiovascular disease accounts for 20.6% of all the cases requiring nursing care, and the annual medical costs exceed 6 trillion yen. [2,3] The Japanese government has approved the Japanese National Plan for Promotion of Measures Against Cerebrovascular and Cardiovascular Disease in 2020. This Japanese National Plan promotes the establishment of a comprehensive community care system that encompasses health, medical care, welfare, nursing care, and the sharing of evidence-based information. [4,5]

Among cardiovascular diseases, heart failure (HF) is increasing with the ageing of the population, with the number of patients in Japan expected to exceed 1.3 million by 2030. [6,7] Heart failure reduces the quality of life of patients and their families by repeated rehospitalizations due to exacerbations, and the increased burden of medical expenses. [8-10] The one-year readmission rate for heart failure patients is 35% in Japan, but a study of elderly heart failure patients in the United States reported a rate of 64%. [11,12] Elderly heart failure patients have multiple comorbidities, such as atrial fibrillation, chronic renal failure, dementia, and depression, which are factors associated with readmission. [13] In addition, many factors have been reported to be associated with readmission in heart failure patients, including cognitive function, depression/anxiety, exercise tolerance, muscle strength, walking speed, activities of daily living (ADL), and instrumental activities of daily living (IADL). [14-18] The Guideline on Diagnosis and Treatment of Acute and Chronic Heart Failure (JCS 2017/ JHFS 2017) recommends that patients with limited self-care capabilities, such as elderly patients with heart failure, should receive education and support from their families and actively utilise social resources such as home physicians and home-visit nursing. [19] Social support and information sharing in the community have been reported to prevent HF readmissions, and there is an urgent need to establish an information sharing system between medical professionals and care professionals in the community. [20,21]

The Japanese Society of Heart Failure recommends the use of the International Classification of Functioning, Disability and Health (ICF) for comprehensive assessment and multidisciplinary information sharing in elderly patients with heart failure. [22] The ICF was introduced by the WHO in 2001; it aims to provide a framework for health and health-related conditions. The ICF is expected to be used as a common language for patients, their families, medical professionals, and caregivers. [23] However, ICF has not been widely used in clinical practice. [24] Thus, we selected 43 ICF categories according to previous studies for a comprehensive assessment of older patients with heart failure.

[25,26] The 43 ICF categories specific to older patients with heart failure consisted of 17 body functions and one body structure, 19 activities and participation in the same, and 6 environmental factors. However, in order to utilise a comprehensive assessment based on the ICF in clinical practice, it is necessary to develop guidelines for the assessment of the 43 ICF categories and to verify their appropriateness.

The purpose of this study was to develop a scoring method of older patients with heart failure based on the ICF, and to determine its appropriateness using the Delphi technique.

METHOD

Patient and public involvement

Patients and the public are not involved in the design, planning, conduct or reporting of this study.

Design

We applied the Delphi method to an expert panel. The Delphi method is a consensus method used in the development of guidelines and clinical indicators, and is effective in guiding assessments and treatments for which there is limited evidence. The Delphi method is also a standard practice in the development of ICF Core Sets. [27] We developed a questionnaire based on the literature review and structured a two-stage survey with an expert panel, referring to the RAND/UCLA appropriateness methodology. [28] (Figure 1).

Establishing of the expert panel

The expert panel consisted of multidisciplinary professionals working in primary care, elderly care, home and community health care, and paramedical services. All members of the expert panel are experts in the assessment, treatment, and care of older patients with heart failure. To coordinate the panel, we used the networks of the Hiroshima Prefecture Association of Care Managers and the Hiroshima Heart Health Promotion Project. [29] The panel consisted of 26 members: five general practitioners, two cardiovascular physicians, 10 care managers, three nurses, one pharmacist, two physical therapists, one occupational therapist, one nutritionist, and one social worker.

Development of the Delphi questionnaire

We developed scoring guidelines and linking of the assessment batteries to the 43 ICF categories selected from previous studies by medical professionals and care professionals. [25,26] To develop the questionnaire, we first conducted a literature

review of the ICF linking rules. The ICF linking rules are a systematic methodology for linking the existing assessment batteries to the ICF codes. [30,31] All articles related to the ICF linking rule from January 2005 to August 2020 were included in the study. We used MEDLINE (PubMed), Cochrane Library, CINAHL, and PsycoInfo as electronic article databases. The search terms in the electronic article database were "ICF" and "Linking rule" or "Rasch" in medical subject headings (MeSH). The search criteria were as follows: (1) written in English, (2) cross-sectional study, cohort study, or case-control study, (3) target group of people aged 18 years or older, (4) use of an existing evaluation battery, (5) results from ICF data or Rasch analysis of the ICF data, and (6) "ICF" and "linking rule" present in the title. The literature review was carried out by five authors (SS, NG, HF, SN, and YT) in two phases. In the first phase, the appropriateness of the titles and abstracts were assessed based on the search criteria. In the second phase, the full text was assessed. Finally, we carried out a qualitative analysis of articles to identify links to assessment batteries and scoring systems associated with the 43 ICF categories. We completed the questionnaire based on the results of this literature review and the explanatory notes in the ICF Reference Guide. [32,33] The Delphi questionnaire consisted of the following three questions regarding the appropriateness of the 43 ICF categories as follow; (i) the grade guidelines, (ii) the evaluation battery linked to the ICF categories, and (iii) the scoring guidelines for the evaluation battery linked to the ICF categories. All questionnaires were developed using a Google Form, with a description of each ICF category and the rationale for scoring.

Delphi process and funding consensus

The Delphi process for reaching a consensus is shown in Figure 1. Before conducting the Delphi survey, the Heart Failure Center (HFC) held an online meeting for the panel members. In the online meeting, we explained the purpose of our study and the methods of the Delphi process to the panel members and obtained their consent to participate in the study. In the Delphi study, the panel members assessed the appropriateness of the following questionnaire items: (1) guidelines for scoring the 43 ICF categories for elderly patients with heart failure, (2) a rating battery linked to the ICF categories, and (3) guidelines for scoring the linked rating battery. To assess the appropriateness, we used a nine-point Likert scale ranging from 1 (very inappropriate) to 9 (very appropriate). Panel members were also asked to freely describe the items that they thought needed revision.

In the first round, the HFC mailed a sheet with instructions on how to conduct the ICF category adequacy assessment, as well as the URL and QR codes for the questionnaire. The panel members rated the "appropriateness" of the questions in each ICF category

on a scale of 1 to 9. The HFC had the panel members tabulate their responses and they modified the questionnaire based on the panel's comments. In the second round, the HFC emailed the revised questionnaire and feedback based on the panel members' responses. As in the first round, the panel members rated the appropriateness of all the ICF category questions and wrote freely about items that they thought needed to be modified. The HFC compiled the panel members' responses and assessed their appropriateness. We also modified the questionnaire based on the panel's comments. The revised questionnaire was emailed to the panel members, and a final consensus was reached after confirming that there were no comments for revision.

Analysis

Guided by the RAND/UCLA appropriateness methodology.[28], we used the median of the responses from the panellists to assess appropriateness. Appropriateness was evaluated on the following three levels: "Appropriate", a median panel value of 7-9 with no disagreement; "Uncertain", a median panel value of 4-6, or any median value with which there is no disagreement; "Inappropriate", a median panel value of 1-3, with no disagreement. The definition of agreement consent is defined as follows: "Agreement", 80% or more of the respondents' medians are within the same region (1-3, 4-6, 7-9) as the median.

Ethics

This study was conducted in accordance with the principles of the Declaration of Helsinki. We explained the purpose and content of the study in writing and at online meetings to the expert panel members who participated in the study and obtained their written consent. The received data was processed after deleting personal information (names). Approval was obtained from the Ethical Review Committee for Epidemiological Research, Hiroshima University (Approval No: E-2580). This study was supported by the MHLW Comprehensive Research on Statistical Information Program, Grant Number JPMH20AB1002.

RESULTS

Characteristics of the expert panel participants

A total of 26 experts agreed to participate in the study. In the first round, 24 of the 26 invited experts responded to the questionnaire. In the second Delphi round, 21 experts responded to the questionnaires. Table 1 shows the characteristics of the experts who responded to all Delphi rounds.

Table 1 Characteristics of the expert panel participants (n = 21)

Characteristics	n (%)
Sex	
Male	8 (38.1)
Female	13 (61.9)
Professions	
Home physicians	4 (19.0)
Cardiovascular physicians	1 (4.8)
Care managers	9 (42.8)
Nurses	3 (14.3)
Pharmacist	1 (4.8)
Physical therapists	2 (9.5)
Occupational therapist	1 (4.8)
Type of facilities	
Hospital: Acute care ward	6 (28.6)
Hospital: Rehabilitation ward	2 (9.5)
Clinic	4 (19.0)
Regional comprehensive support centre	2 (9.5)
Community care centre/Home nursing station	6 (28.6)
Municipal office	1 (4.8)

Development of the Delphi questionnaire of ICF assessment method for older patients with heart failure

A total of 409 references were extracted from the literature survey. The breakdown of each article database was as follows: MEDLINE (PubMed), 230 articles; Cochrane Library, 0 articles; CINAHL, 107 articles; PsycInfo, 72 articles. In the primary screening, 107 references were extracted, and in the secondary screening, 26 references were extracted. Finally, two references were excluded, and the total number of eligible references was 26. In the qualitative analysis, we excluded articles dealing with assessment batteries such as stroke, musculoskeletal diseases, hand surgery, and low back pain, whose relevance to older heart failure patients was not clear. As a result, eight articles addressed assessment batteries linked to the 43 ICF categories in older patients with heart failure. [34-41] (Figure 2). More than half of the assessment batteries used in the eight references were ADL assessments such as Functional Independence Measure (FIM) and Barthel Index (BI), and general quality of life assessments such as Short Form

36 and Euro Qol-5D.

Based on the literature review, the evaluation battery corresponding to the ICF categories was selected, and the grade guidelines were determined. We have explained the scoring guideline clearly and briefly, based on the ICF Reference Guide. [32,33] We referred to the Italian ICF guidelines. [42] for ICF categories not covered in the literature review. In addition, we adopted a widely used clinical assessment battery and developed our own grading guidelines. Finally, we decided to provide 30 of the 43 ICF categories with a rating battery to assist in scoring, while the remaining 13 ICF categories were scored using only the scoring guidelines (Table 2).

Delphi round 1

From February to March of 2021, 24 panel members (92.3%) responded to Round 1 of the Delphi process. Panel members assessed the appropriateness of the following three items for the 43 ICF categories: (1) the scoring guidelines, (2) the assessment battery of supplementary criteria, and (3) scoring guidelines for the assessment battery of supplementary criteria. As a result, we found that all 43 ICF categories had a median of 7-9, but for 26 ICF categories the tertile 7-9% was less than 80% and was not considered a consensus. We revised the descriptions and scoring criteria for the 26 ICF categories for which we could not reach a consensus, and based on panel members' opinions we developed a questionnaire for Round 2.

Delphi round 2

From April to May of 2021, we emailed the revised questionnaire to the 24 panel members who responded to Round 1. 21 panel members (87.5%) responded to the Round 2 questionnaire. There was less score variability in Round 2 than in Round 1, with a median of 7-9 in all 43 ICF categories (Table 2). We found the tertile 7-9% to be above 80% in all ICF categories except for the guideline for the supplementary criterion of category d450 walking. Based on the respondents' feedback, we modified the supplementary criteria for ICF category d450 walking to exclude 5 meters walking speed and to score only FIM. After modifying the ICF category d450, we sent the manual of the modified assessment method by e-mail to all panel members who participated in Round 2, asking for their comments, and confirming that we had reached a consensus.

Table 2: Results of the 43 ICF categories in the second Delphi round.

ICF categories		Evaluation battery as supplementary criterion	Scoring guidelines		Evaluation battery adopted for the supplementary ICF categories		Guidelines for scoring the supplementary criteria	
			median	Tertile 7-9 (%)	median	Tertile 7-9 (%)	median	Tertile 7-9 (%)
b110	Consciousness function	Japan Coma Scale	8	85.7	9	90.5	9	95.2
b114	Orientation function	Mimi-Mental State Examination	8	85.7	8	81.0	9	90.5
b130	Energy and drive function	Vitality Index	8	90.5	8, 9	85.7	8, 9	90.5
b134	Sleep function	Pittsburgh Sleep Quality Index	8	90.5	9	90.5	9	81.0
b164	Higher-level cognitive functions	Frontal Assessment Battery	7	90.5	8	90.5	9	85.7
b410	Heart function	Echocardiography; left ventricular function, Electrocardiogram	7, 8	81.0	9	85.7	8, 9	85.7
b415	Blood vessel function	Fontaine classification	7, 8	81.0	7, 9	90.5	9	81.0
b420	Blood pressure function	Blood pressure	7, 8	81.0	9	95.2	9	90.5
b440	Respiration function	SpO_2, Respiration Rate	8	90.5	8	85.7	8	95.2
b455	Exercise tolerance function	Specific Activity Scale	9	90.2	9	85.7	9	95.2
b460	Sensations associated with cardiovascular and respiratory functions	NYHA classification	9	90.5	9	95.2	9	95.2
b525	Defaecation function	-	8	85.7	-	-	-	-
b530	Weight maintenance functions	Body Mass Index	8	85.7	9	85.7	9	85.7
b545	Water, mineral and electrolyte balance functions	Blood test: Na, K	7, 9	81.0	7, 9	85.7	7	85.7
b620	Urination function	-	8	81.0	-	-	-	-
b710	Mobility of joint function	Range Of Motion	8	85.7	8	85.7	7, 8	90.5
b730	Muscle power function	Manual Muscle Test or five-times sit-to-stand	8	85.7	7	85.7	8	81.0
s410	Structure of the cardiovascular system	Echocardiography; Severity of valve function	7	85.7	7	85.7	7	90.5

		Chest radiograph; CTR						
d177	Making decisions	-	8	85.7	-	-	-	-
d230	Carrying out daily routine	-	8	90.5	-	-	-	-
d310	Communicating with-receiving-spoken messages	FIM; Comprehension	8	90.5	9	95.2	9	95.2
d330	Speaking	FIM; Expression	8	90.5	9	95.2	9	90.5
d420	Transferring oneself	FIM; Transfers	8	95.2	8	95.2	8	95.2
d450	Walking	FIM; Walk 5-m walk test	8	95.2	8	90.2	8	76.2
d510	Washing oneself	FIM; Bathing	7	95.2	8, 9	95.2	7	95.2
d520	Caring for body parts	FIM; Grooming	8	95.2	7, 9	90.2	7, 9	95.2
d530	Toileting	FIM; Toileting	7	90.2	9	90.2	7	85.7
d540	Dressing	FIM; Dressing	7	95.2	8	95.2	7	95.2
d550/ d560	Eating/ Drinking	FIM; Eating	8	95.2	8	90.5	9	85.7
d570	Looking after one's health	-	8	85.7	-	-	-	-
d620	Acquisition of goods and services	Instrumental Activities of Daily Living scale; Shopping	8	81.0	8	85.7	8	85.7
d630	Preparing meals	Instrumental Activities of Daily Living scale; Food preparation	8	90.5	8	95.2	8	85.7
d640	Doing housework	Instrumental Activities of Daily Living scale; Housekeeping	8	81.0	8	85.7	8	85.7
d710	Basic interpersonal interactions	-	7, 8, 9	85.7	-	-	-	-
d760	Family relationships	-	7, 8, 9	85.7	-	-	-	-
d920	Recreation and leisure	-	7	90.5	-	-	-	-
e310	Immediate family	-	8	85.7	-	-	-	-
e340	Personal care providers and personal assistants	-	9	90.5	-	-	-	-
e355	Health professionals	-	8	95.2	-	-	-	-
e410	Individual attitudes of immediate family members	-	8	90.5	-	-	-	-
e575	General social support services, systems, and policies	-	8	90.5	-	-	-	-
e580	Health services, systems, and policies	-	7	85.7	-	-	-	-

SpO2, oxygen saturation; NYHA, New York Heart Association; CTR, cardiothoracic ratio; FIM, Functional Independence Measure.

DISCUSSION

We have developed a comprehensive assessment of older people with heart failure for widespread use in clinical practice and validated the scoring method using the RAND Delphi method. The results of the two-round Delphi process were judged to be "appropriate" in all 43 ICF categories of questions and "agreement" in all 43 ICF categories, except for the scoring guidelines for supplementary criteria for d450 walking. In the d450 walking, we had to reach a consensus through the modifications based on the panel members' comments.

The purpose of this study was to develop an assessment method that could be used not only by cardiologists but also by medical professionals: general practitioners, care managers and paramedical professions. Therefore, we adopted a simple evaluation method that requires as little special machinery and environment as possible. For example, although exercise tolerance at b455 has been reported to be a prognostic factor for heart failure.[43], we avoided cardiopulmonary exercise testing (CPX). [44-46] and the 6-minute walk test. [47] and chose specific activity scale (SAS) instead. [48] In the d450 walking, we used two assessment batteries, gait speed and FIM, as supplementary criteria, but the agreement rate did not exceed 80% in the second Delphi study. Although gait speed is a prognostic factor for heart failure patients over 65 years of age.[16], we adopted FIM only as an auxiliary criterion for simplicity of assessment, and obtained a consensus from the panel members. However, the 43 items in the current ICF did not include renal function, BNP, and anaemia, which are prognostic factors for heart failure. [49] We suggest that these items be added, although the increase in the items may prevent their wide-spread use in the clinical setting, making their clinical use more difficult. In addition, the 43 ICF categories assessment instrument developed in this study did not include personal factors such as age, sex, values, lifestyle, coping, and personality. In the care of chronic diseases, patient-centred intervention is the principle.[50], and patient-centred care is also recommended in the ESC guidelines. [51] We propose that personal factors need to be included when developing an ICF information-sharing system.

In Japan, the establishment of a comprehensive community care system that integrates medical care, welfare, and nursing care is being promoted, but evidence for information

sharing is lacking. We expect that the ICF-based assessment method for older patients with heart failure developed in this study will be widely used in clinical practice.

Strengths and limitations

Since the purpose of this study was to develop a common community-based evaluation method for medical and nursing care, we constructed an expert panel related to medical professions and nursing care professions in Hiroshima prefecture. Since there is no variation in the regions of the panel members, the existence of selective bias cannot be denied. Therefore, we suggest that the results of this study should be used with caution in regions other than Hiroshima prefecture. This study was based on the RAND/UCLS Delphi method, but face-to-face meetings could not be conducted because of the current coronavirus pandemic. Therefore, the implementation is not strictly based on the RAND/UCLS method. We believe that we should have held an online meeting during the Delphi Round 2. In this study, the Delphi method through expert consensus was used to clarify the appropriateness of the evaluation method. The shortcomings of the Delphi method are the possibility of coercion and inducement to gather opinions and the issue of the validity of the questionnaire. In the future, it will be necessary to clarify the validity of the evaluation method in survey studies of elderly people with heart failure.

Implications and Future directions

The results of this study have two implications. First, it is the establishment of a comprehensive assessment method for older patients with heart failure, which is a social problem in Japan. Comprehensive multidisciplinary assessment is important to prevent rehospitalization for heart failure, and the ICF-based scoring method developed in this study is expected to prevent rehospitalization. Second, the ICF-based evaluation method allows for an international comparison of the effectiveness of heart failure treatment and information sharing. Wagner proposes a patient-centred model for chronic disease care that utilises local social resources and information sharing systems such as information and communication technology (ICT). [52,53] In the future, it is necessary to establish an information sharing system using a comprehensive assessment method based on the ICF, and to examine the effect of readmission prevention and differences in life function according to local policies.

CONCLUSION

We developed a scoring method based on the ICF for elderly heart failure patients and

clarified its appropriateness using the Delphi method. Future work is required to develop an ICF-based information sharing system and to clarify its impact on the prevention of re-hospitalisation and quality of life in older patients with heart failure

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Contributions

All authors meet the criteria for authorship of the ICMJE. SS, TK, TH and HK contributed to the conceptualisation of the study. SS, NG, HF, SN, YT, NM, KK, MN and MY were responsible for designing the questionnaire and collecting and analysing the data. MN, MY, MM, HO and YY were responsible for recruiting the study participants. YN, YK and HK were responsible for interpreting the results and managing the project. SS and HK supervised all research activities. All authors reviewed the current draft and approved the final current submission.

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Competing interests

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Ethics approval

The study was approved by the Hiroshima University of Epidemiological Research Ethics Review Board (approval number: E-2217).

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ORCID iD
Shigehito Shota https://orcid.org/0000-0001-7186-2327

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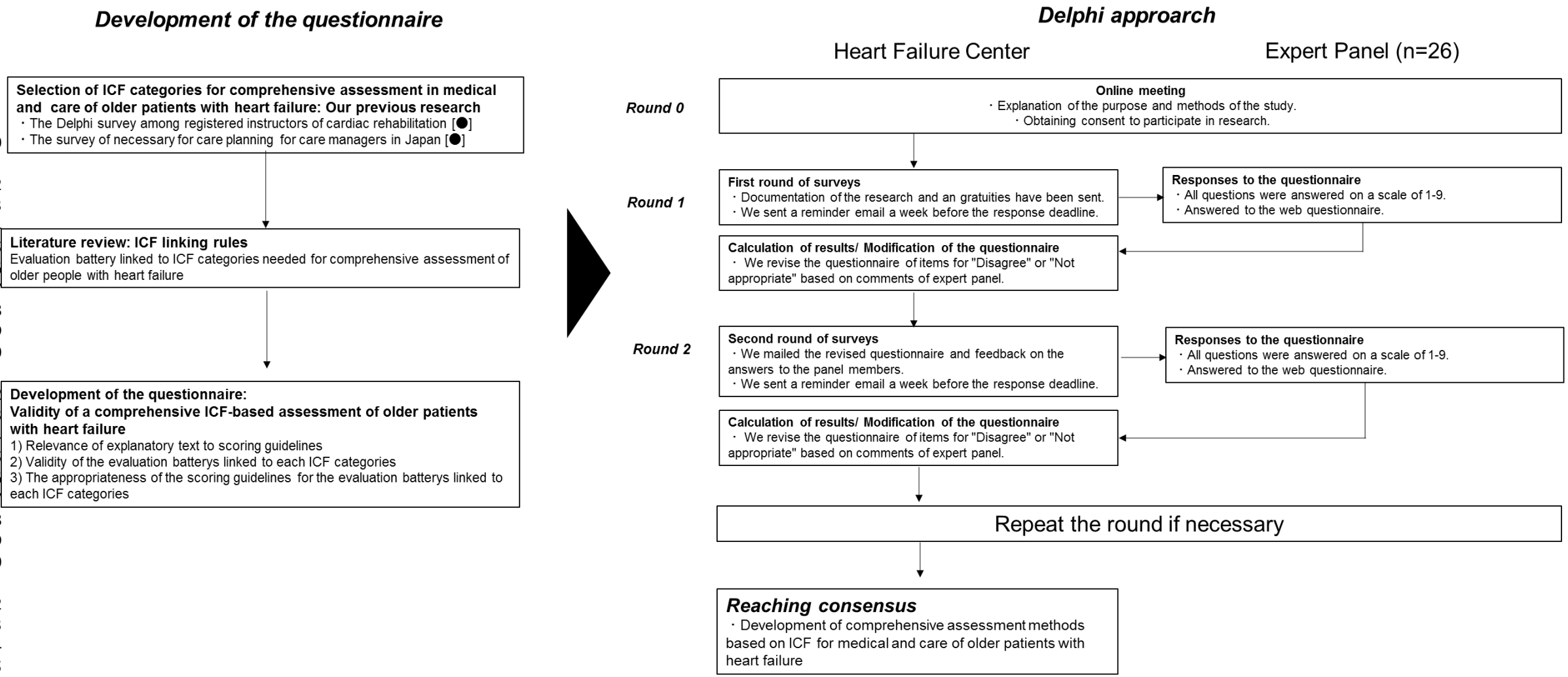
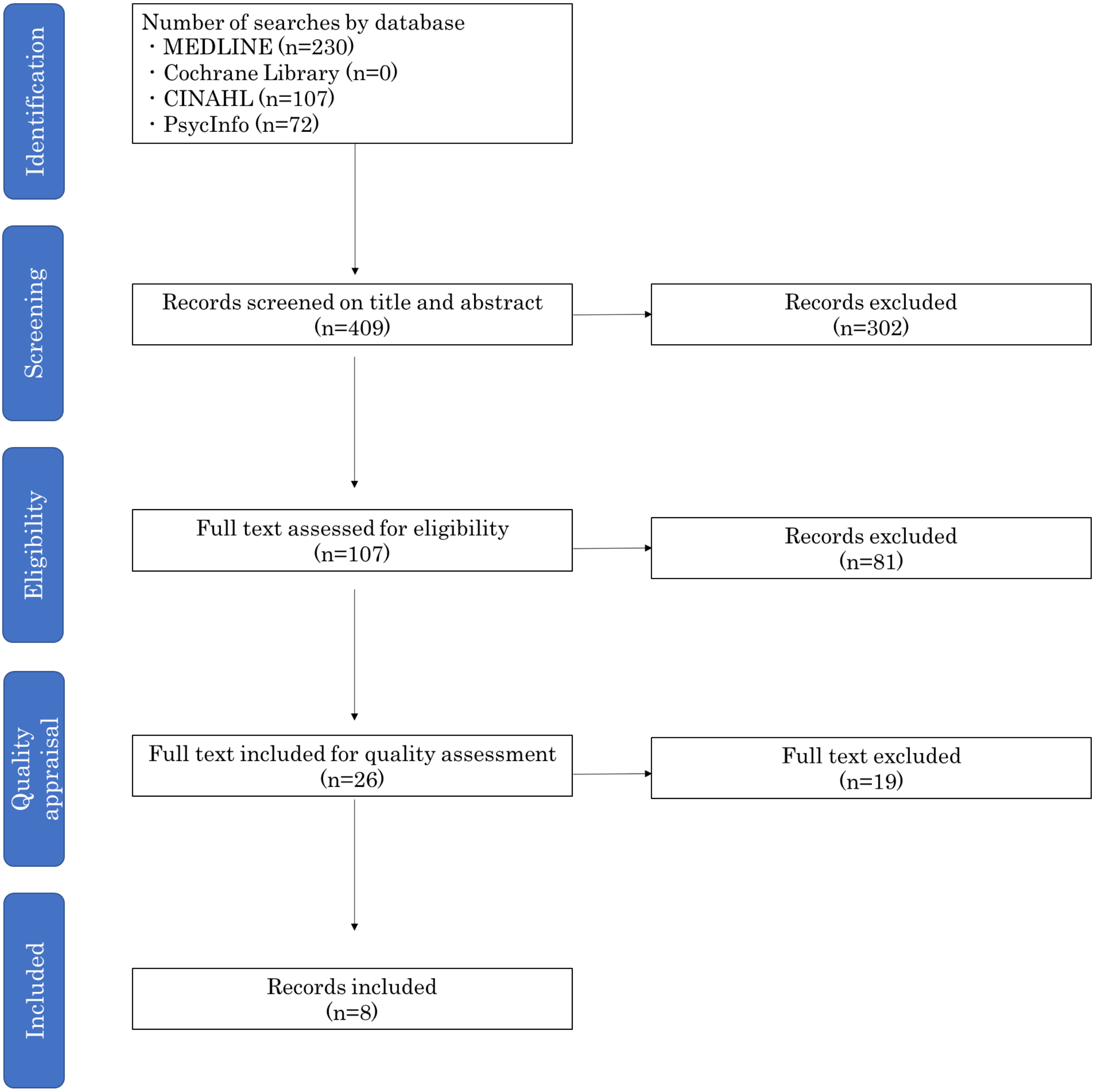
Figure Legends

Fig. 1: Development of Questionnaire and Delphi process flow

Fig. 2: Selection of records and process flow diagrams


Development of the questionnaire
Selection of ICF categories for comprehensive assessment in medical and care of older patients with heart failure: Our previous research
・The Delphi survey among registered instructors of cardiac rehabilitation [●]
・The survey of necessary for care planning for care managers in Japan [●]
Literature review: ICF linking rules
Evaluation battery linked to ICF categories needed for comprehensive assessment of older people with heart failure
Development of the questionnaire:
Validity of a comprehensive ICF-based assessment of older patients with heart failure
1) Relevance of explanatory text to scoring guidelines
2) Validity of the evaluation batterys linked to each ICF categories
3) The appropriateness of the scoring guidelines for the evaluation batterys linked to each ICF categories
Delphi approarch
Heart Failure Center
Expert Panel (n=26)
Round 0
Online meeting
・Explanation of the purpose and methods of the study.
・Obtaining consent to participate in research.
Round 1
First round of surveys
・Documentation of the research and an gratuities have been sent.
・We sent a reminder email a week before the response deadline.
Responses to the questionnaire
・All questions were answered on a scale of 1-9.
・Answered to the web questionnaire.
Calculation of results/ Modification of the questionnaire
・We revise the questionnaire of items for "Disagree" or "Not appropriate" based on comments of expert panel.
Round 2
Second round of surveys
・We mailed the revised questionnaire and feedback on the answers to the panel members.
・We sent a reminder email a week before the response deadline.
Responses to the questionnaire
・All questions were answered on a scale of 1-9.
・Answered to the web questionnaire.
Calculation of results/ Modification of the questionnaire
・We revise the questionnaire of items for "Disagree" or "Not appropriate" based on comments of expert panel.
Repeat the round if necessary
Reaching consensus
・Development of comprehensive assessment methods based on ICF for medical and care of older patients with heart failure


Identification
Number of searches by database
・MEDLINE (n=230)
・Cochrane Library (n=0)
・CINAHL (n=107)
・PsycInfo (n=72)
Screening
Records screened on title and abstract (n=409)
Records excluded (n=302)
Eligibility
Full text assessed for eligibility (n=107)
Records excluded (n=81)
Quality appraisal
Full text included for quality assessment (n=26)
Full text excluded (n=19)
Included
Records included (n=8)

BMJ Open

Development and appropriateness of a scoring method for International Classification of Functioning, Disabilities, and Health assessment in older patients with heart failure: a Delphi survey of expert panel in Japan

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Keywords:	Heart failure < CARDIOLOGY, REHABILITATION MEDICINE, PUBLIC

	HEALTH, GERIATRIC MEDICINE

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Original research

Development and appropriateness of a scoring method for International Classification of Functioning, Disabilities, and Health assessment in older patients with heart failure: a Delphi survey of expert panel in Japan

Shigehito Shiota[1,2], Toshiro Kitagawa[1,3], Naoya Goto[2], Hironori Fujisita[2], Yurika Tamekuni[2], Susumu Nakayama[4], Naoki Mio[1,2], Kana Kanai[1,2], Makiko Naka[1], Mizuho Yamaguchi[1], Mariko Mochizuki[5], Hiroyuki Ochikubo[5], Takayuki Hidaka[6], Yuji Yasunobu[7], Yukiko Nakano[1,3], Yasuki Kihara [8], Hiroaki Kimura[1,9]

[1] Heart Failure Centre, Hiroshima University Hospital, Hiroshima, Japan

[2] Division of Clinical Support, Department of Rehabilitation, Hiroshima University Hospital, Hiroshima, Japan

[3] Hiroshima University Graduate School of Biomedical and Health Sciences, Hiroshima, Japan

[4] Home nursing station Sakurazaka, Hiroshima, Japan

[5] Hiroshima Care Manager Association, Hiroshima, Japan.

[6] Department of Cardiovascular Medicine, Hiroshima Prefectural Hospital, Hiroshima, Japan

[7] Department of Cardiovascular Medicine, Miyoshi Medical Association Hospital, Hiroshima, Japan

[8] Hiroshima University Graduate School of Biomedical and Health Sciences, Hiroshima, Japan

[9] Department of Rehabilitation Medicine, Hiroshima University Hospital, Hiroshima, Japan

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Corresponding author:

Shigehito Shiota

Email: sshiota@hiroshima-u.ac.jp

Address: 1-2-3, Kasumi, Minami-ku, Hiroshima City, Hiroshima, Japan

ABSTRACT

Objective: The number of older patients with heart failure (HF) is increasing in Japan and has become a social problem. There is an urgent need to develop a comprehensive assessment methodology based on the common language of health care; the International Classification of Functioning, Disability and Health (ICF). The purpose of this study was to develop and confirm the appropriateness of a scoring methodology for 43 ICF categories in older people with HF.

Design: Cross-sectional survey. We applied the RAND/UCLA Appropriateness Method with a modified Delphi method.

Setting and participants: We included a panel of 26 multidisciplinary experts on HF care consisting of home physicians, cardiovascular physicians, care managers, nurses, physical therapists, a pharmacist, occupational therapist, nutritionist, and a social worker.

Measures: We conducted a literature review of ICF linking rules and developed a questionnaire on scoring methods linked to ICF categories in older people with HF. In the Delphi rounds, we sent the expert panel a questionnaire consisting of three questions for each of the 43 ICF categories. The expert panel responded to the questionnaire items on a 1 (very inappropriate) – 9 (very appropriate) Likert scale and repeated rounds until a consensus of 'Appropriate' and 'Agreement' was reached on all items.

Results: A total of 21 panel members responded to all the Delphi rounds. In the first Delphi round, six question items in four ICF categories did not reach a consensus of 'Agreement', but the result of our modifications based on panel members' suggestions reached to a consensus of 'Appropriate' and 'Agreement' on all questions in the second Delphi round.

Conclusion: The ICF-based scoring method for older people with HF developed in this study was found to be appropriate. Future work is needed to clarify whether comprehensive assessment and information sharing based on ICF contributes to preventing readmissions.

Keywords: heart failure, older people, ICF, scoring methods, RAND/UCLA Appropriateness Method

Strengths and limitations of this study

►An expert panel familiar with heart failure care, consisting of home physicians, care managers, and multidisciplinary medical professionals, rated the "appropriateness" of the questions in each ICF category through a multiple-round process to reach a consensus.

► The assessment domains studied the 43-item ICF relevant to older adults with heart failure, covering not only the medical assessment but also the physical and mental functioning, activity and social participation, and environmental factors.

►The expert panel comprised general practitioners, cardiologists, and paramedical professions (rehabilitation, nursing care, and welfare), but caution is needed in generalizing the findings because of the study's limited geographical area.

INTRODUCTION

In Japan, cardiovascular disease is the second leading cause of death. [1] In addition, cardiovascular disease accounts for 20.6% of all cases requiring nursing care, and the annual medical costs exceed 6 trillion yen (USD 46 billion). [2,3] The Japanese government has approved the Japanese National Plan for Promotion of Measures Against Cerebrovascular and Cardiovascular Disease in 2020. This Japanese National Plan promotes the establishment of a comprehensive community care system that encompasses health, medical care, welfare, nursing care, and the sharing of evidence-based information. [4,5]

Among cardiovascular diseases, heart failure (HF) is increasing with the ageing of the population, with the number of patients in Japan expected to exceed 1.3 million by 2030. [6,7] HF reduces the quality of life of patients and their families by repeated rehospitalizations due to exacerbations, and the increased burden of medical expenses. [8-10] The one-year readmission rate for patients with HF is 35% in Japan, but a study of elderly patients with HF in the United States reported a rate of 64%. [11,12] Elderly patients with HF have multiple comorbidities, such as atrial fibrillation, chronic renal failure, dementia, and depression, which are factors associated with readmission. [13] In addition, many factors have been reported to be associated with readmission in patients with HF, including cognitive function, depression/anxiety, exercise tolerance, muscle strength, walking speed, activities of daily living (ADL), and instrumental activities of daily living (IADL). [14-18] The Guideline on Diagnosis and Treatment of Acute and Chronic Heart Failure (JCS 2017/ JHFS 2017) recommends that patients with limited self-care capabilities, such as elderly patients with HF, should receive education and support from their families and actively utilise social resources such as home physicians and home-visit nursing. [19] Social support and information sharing in the community have been reported to prevent HF readmissions, and there is an urgent need to establish an information sharing system between medical professionals and care professionals in the community. [20,21]

The Japanese Society of Heart Failure recommends the use of the International Classification of Functioning, Disability and Health (ICF) for the comprehensive assessment and multidisciplinary information sharing in elderly patients with HF. [22] The ICF was introduced by the WHO in 2001; it aims to provide a framework for health and health-related conditions. The ICF is expected to be used as a common language for patients, their families, medical professionals, and caregivers. [23] However, the ICF has not been widely used in clinical practice because of the complexity of the coding and the unreliability of the scores. [24-28] To promote the use of the ICF in clinical practice, the

World Health Organisation provides the ICF Core Set and the ICF Linking Rules. The ICF Core Set is a set of identified ICF categories for assessing a patient's special health condition or special medical background. [29] The ICF Linking Rules are a method of linking ICF categories with existing assessment methods. [30,31] The ICF core set for chronic ischaemic heart disease and the Geriatric ICF core set have already been developed, but these ICF categories are not appropriate for adaptation to older patients with heart failure. [32,33] Therefore, 43 ICF categories were selected for the comprehensive assessment of older patients with HF through the questionnaire survey of a multidisciplinary group of medical professionals and care professionals. [34,35] The 43 ICF categories specific to older patients with HF consisted of 17 body functions and one body structure, 19 activities and participation, and 6 environmental factors. However, in order to efficiently utilize ICF-based assessments in clinical practice, it is necessary to develop scoring methods linked to existing assessments.

The purpose of this study was to develop a scoring method of older patients with HF based on the ICF, and to determine its appropriateness using the Delphi technique.

METHOD

Patient and public involvement

Patients and the public are not involved in the design, planning, conduct or reporting of this study.

Design

We applied the Delphi method to an expert panel. The Delphi method is a consensus method used in the development of guidelines and clinical indicators, and is effective in guiding assessments and treatments for which there is limited evidence. The Delphi method is also a standard practice in the development of ICF Core Sets. [29] We developed a questionnaire based on the literature review and structured a two-stage Delphi survey with an expert panel, referring to the RAND/UCLA appropriateness methodology. [36] (Figure 1).

Establishing of the expert panel

We established an expert multidisciplinary panel consisting of 26 medical and care professionals in Hiroshima Prefecture, Japan. The members of the expert committee were professionals with leadership roles in community care, all of whom have expertise in the assessment, treatment, and care of older patients with heart failure. Five home physicians and ten care managers were recommended by the Hiroshima Care Manager

Association. All five home physicians are specialists in internal medicine who engage in home visits while all ten care managers are board members of the Hiroshima Care Manager Association and leaders in their respective communities. In addition, we included 11 medical multidisciplinary professionals involved in HF care at specialised medical institutions recommended by the Hiroshima Heart Health Promotion Project in our panel .[37] The 11 medical multidisciplinary members were: two cardiovascular physicians, three nurses certified in chronic HF nursing, two physiotherapists with registered instructors of cardiac rehabilitation, one occupational therapist with registered instructors of cardiac rehabilitation, one certified pharmacist, one nutritionist, and one social worker.

Development of the questionnaire

We developed scoring methods for the 43 ICF categories linking to existing assessment batteries. [34,35] To develop the questionnaire, we first conducted a literature review of the ICF linking rules. The ICF linking rules are a systematic methodology for linking the existing assessment batteries to the ICF codes. [30,31] All articles related to the ICF linking rule from January, 2005 to August, 2020 were included in the study. We used MEDLINE (PubMed), Cochrane Library, CINAHL, and PsycoInfo as electronic article databases. The search terms in the electronic article database were "ICF" and "Linking rule" or "Rasch" in medical subject headings (MeSH). The search criteria were as follows: (1) written in English, (2) cross-sectional study, cohort study, or case-control study, (3) target group of people aged 18 years or older, (4) use of an existing assessment battery, (5) results from ICF data or Rasch analysis of the ICF data, and (6) "ICF" and "linking rule" present in the title. The literature review was carried out by five authors (SS, NG, HF, SN, and YT) in two phases. In the first phase, the appropriateness of the titles and abstracts were assessed based on the search criteria. In the second phase, the full text was assessed. Finally, we conducted a qualitative analysis of the articles to select an assessment battery that could be adapted to older patients with HF and to clarify its association with the 43 ICF categories. We completed the questionnaire based on the results of this literature review and the explanatory notes in the ICF Reference Guide. [38,39] We set three questions for each of the 43 ICF categories and prepared 1 (very inappropriate) - 9 (very appropriate) Likert scale responses to assess appropriateness. Appropriateness was evaluated on a median response scale with the following three levels: 1-3 as “inappropriate”, 4-6 as “uncertain”, and 7-9 as “appropriate”. The three questionnaire items were as follows: 1) Appropriateness of the 43 ICF category scoring descriptions, 2) appropriateness of

existing assessment batteries linked to each ICF categories, and 3) appropriateness of the scoring methods for each ICF categories linked to existing assessment batteries. All questionnaires were developed using a Google Form, with a description of each ICF category and the rationale for scoring. (Supplemental materials 1).

Delphi process and funding consensus

The Delphi process for reaching a consensus is shown in Figure 1. Before conducting the Delphi survey, the HF Centre (HFC) held an online meeting for the panel members. In the online meeting, we explained the purpose of our study and the methods of the Delphi process to the panel members and obtained their consent to participate in the study. In the first round, the HFC mailed a sheet with instructions on how to conduct the ICF category adequacy assessment, as well as the URL and QR codes for the questionnaire. The panel members responded to three questions in 43 ICF categories on a scale of 1-9. In addition, panel members provided open-ended suggestions for improvements to the questions they scored 1-6. The HFC collated the panel members' responses. We revised the scoring descriptions and existing assessment batteries linked to the ICF categories responded to as 'Inappropriate', 'Uncertain' or 'Disagreement' based on the panel's suggestions. The definition of 'Disagreement' in this article is given in Analysis. In the second round, the HFC emailed the revised questionnaire and feedback based on the panel members' responses. As in the first round, the panel members rated the appropriateness of three question items in the 43 ICF categories. In addition, the panel members provided suggestions for improvements to the scoring methods on those ones scored 1-6. The HFC compiled the panel members' responses and assessed their appropriateness. We also revised the descriptions of the questionnaire or scoring methods based on the panel's suggestions. The revised questionnaire was emailed to the panel members, and a final consensus was reached after confirming that there were no comments for revision.

Analysis

Following the RAND/UCLA appropriateness methodology [28], we used the median scores of the responses from the panellists to assess appropriateness. We rated the appropriateness of the 43 ICF categories for the assessment method as 'Appropriate' if the median respondent's score was 7-9, 'Uncertain' if it was 4-6 and 'Inappropriate' if it was 1-3. In accordance with the RAND/UCLA guidelines, we defined 'Agreement' or 'Disagreement' according to the number of panellists who rated outside the range of tertiles (1-3; 4-6; 7-9) including the median. 'Agreement' was defined as fewer than one-

third of panellists who rated outside the range of the tertile values. 'Disagreement' was defined as when more than one-third of panellists rated the extremes (1-3 range and 7-9 range) not including the median.

Ethics

This study was conducted in accordance with the principles of the Declaration of Helsinki. We explained the purpose and content of the study in writing and at online meetings to the expert panel members who participated in the study and obtained their written consent. The received data was processed after deleting personal information (names). Approval was obtained from the Ethical Review Committee for Epidemiological Research, Hiroshima University (Approval No: E-2580). This study was supported by the MHLW Comprehensive Research on Statistical Information Program, Grant Number JPMH20AB1002.

RESULTS

Characteristics of the expert panel participants

A total of 26 experts agreed to participate in the study. In the first round, 24 of the 26 invited experts responded to the questionnaire. In the second Delphi round, 21 experts responded to the questionnaires. Table 1 shows the characteristics of the experts who responded to all Delphi rounds.

Table 1 Characteristics of the expert panel participants who responded to all Delphi rounds (n = 21)

Characteristics	n (%)
Sex	
Male	8 (38.1)
Female	13 (61.9)
Professions	
Home physicians	4 (19.0)
Cardiovascular physicians	1 (4.8)
Care managers	9 (42.8)
Nurses	3 (14.3)
Pharmacist	1 (4.8)
Physical therapists	2 (9.5)
Occupational therapist	1 (4.8)
Type of facilities	

Hospital: Acute care ward	6 (28.6)
Hospital: Rehabilitation ward	2 (9.5)
Clinic	4 (19.0)
Regional comprehensive support centre	2 (9.5)
Community care centre/Home nursing station	6 (28.6)
Municipal office	1 (4.8)

Development of the Delphi questionnaire of ICF assessment method for older patients with heart failure

Figure 2 showed the process of literature review. A total of 409 references were extracted from the literature survey. The breakdown of each article database was as follows: MEDLINE (PubMed), 230 articles; Cochrane Library, 0 articles; CINAHL, 107 articles; PsycInfo, 72 articles. In the primary screening, 107 references were extracted, and in the secondary screening, 26 references were extracted. Finally, two references were excluded, and the total number of eligible references was 26. In the qualitative analysis, we excluded 19 references dealing with disease-specific assessment batteries that could not be adapted to older patients with HF (e.g., stroke, musculoskeletal disease, hand surgery, low back pain). Eight articles on ICF linking rules were included. Finally, we employed 11 existing assessment batteries on eight articles links to the 43 ICF categories (Supplemental material 2). [40-47] Eleven existing assessment batteries were included: assessment of ADL (such as Functional Independence Measure (FIM) and Barthel Index), assessment of general health-related quality of life (such as Short Form 36 and the European Quality of Life instrument (EQ-5D), The World Health Organization Quality of Life (WHOQOL)), assessment of general health status (such as the Nottingham Health Profile(NHP), the World Health Organization Disability Assessment Schedule (WHODAS 2.0)), and assessment of falls (such as Falls Efficacy Scale-International (FES-I), the Swedish version of the Falls Efficacy Scale (FES[S]), the Activities-specific Balance Confidence Scale (ABC), and the modified Survey of Activities and Fear of Falling in the Elderly (SAFFE)). We identified these existing assessment batteries as linked to 20 of the 43 categories. However, only the FIM and BI were employed in the questionnaire, as they did not match the objectives of this study for the assessment of general health-related quality of life, general health status and falls. Therefore, we developed a scoring methodology for ICF categories other than ADL, based on the Italian ICF Guidelines and the ICF Reference Guide. [38,39, 48] Finally, we decided to provide 30 existing assessment batteries linking to ICF categories, and to score the remaining 13 categories using only the scoring descriptions (Table 2).

Delphi round 1

From February to March of 2021, 24 panel members (92.3%) responded to Round 1 of the Delphi process. 'Agreement' was defined as when seven or fewer panellists rated outside the range of the three quartiles (1-3; 4-6; 7-9), including the median. 'Disagreement' was defined as eight or more panellists rating the extremes (1-3 range and 7-9 range) that did not include the median. The results of the Delphi round 1 panel members' responses are shown in Supplementary material 3. The median response of panel members was 'appropriate' 7-9 for all three questions in the 43 ICF categories. In the result, 'Agreement' was not reached on six question items in four ICF categories. 'Agreement' was not reached on six questions in four ICF categories. The question items in the ICF categories on which agreement was not reached were 'b134 Sleep functions: 1) scoring descriptions, b410 Heart function: 2) existing assessment batteries and 3) scoring methods linked to ICF categories, s410 Structure of the cardiovascular systems: 2) existing assessment battery and 3) scoring methods linked to ICF categories and d330 Speaking: 2) existing battery of assessments'. We added a scoring method for d134 Sleep function based on the Pittsburgh Sleep Quality Index, based on the panel members' suggestions. For b410 heart function, S410 Structure of cardiovascular system and d330 Speaking, we revised the existing assessment battery and scoring method linked to the ICF categories based on the panel's suggestions.

Delphi round 2

From April to May of 2021, we emailed the revised questionnaire to the 24 panel members who responded to Round 1. Twenty-one panel members (87.5%) responded to the Round 2 questionnaire. 'Agreement' was defined as when six or fewer panellists rated outside the range of the three quartiles (1-3; 4-6; 7-9), including the median. 'Disagreement' was defined as seven or more panellists rating the extremes (1-3 range and 7-9 range) that did not include the median. Table 2 shows the results of the panel members' responses to Delphi Round 2. The results showed that for all ICF category questions, the median responses ranged from 7 to 9 'Appropriate', with all items reaching 'Agreement'. However, as two panel members answered 'Inappropriate' 1-3 for the d450 gait, we modified the existing assessment battery linked to the ICF categories to FIM only, based on members' suggestions. We sent the manual of the modified assessment method by e-mail to all panel members who participated in Round 2, asking for their comments, and confirming that we had reached a consensus.

Table 2: Results of the three questions of the 43 ICF categories in the second Delphi round.

ICF categories		Existing assessment batteries linked to ICF categories	Question Items					
			1) Appropriateness of ICF 43 category scoring descriptions		2) Appropriateness of existing assessment batteries linked to each ICF categories		3) Appropriateness of the scoring methods for each ICF categories linked to existing assessment batteries	
			median score (/9)	Number of outside median tertile (/21)	median score (/9)	Number of outside median tertile (/21)	median score (/9)	Number of outside median tertile (/21)
b110	Consciousness function	Japan Coma Scale	8	3	9	2	8	1
b114	Orientation function	Mimi-Mental State Examination	8	3	8	4	8	2
b130	Energy and drive function	Vitality Index	8	2	8	3	8	2
b134	Sleep function	Pittsburgh Sleep Quality Index	8	2	8	2	7	4
b164	Higher-level cognitive functions	Frontal Assessment Battery	8	2	8	2	8	3
b410	Heart function	Echocardiography; left ventricular function, Electrocardiogram	7	4	8	3	7	3
b415	Blood vessel function	Fontaine classification	8	4	8	2	8	4
b420	Blood pressure function	Blood pressure	8	4	8	1	8	2
b440	Respiration function	SpO_2, Respiration Rate	8	2	8	3	8	1
b455	Exercise tolerance function	Specific Activity Scale	8	2	8	3	8	1
b460	Sensations associated with cardiovascular and respiratory functions	NYHA classification	8	2	8	1	9	1
b525	Defaecation function	-	8	3	-	-	-	-
b530	Weight maintenance functions	Body Mass Index	8	3	8	3	8	3
b545	Water, mineral and electrolyte balance functions	Blood test: Na, K	8	4	8	3	7	3
b620	Urination function	-	8	4	-	-	-	-

b710	Mobility of joint function	Range Of Motion	8	3	8	3	8	2
b730	Muscle power function	Manual Muscle Test or five-times sit-to-stand	8	3	8	3	8	4
s410	Structure of the cardiovascular system	Echocardiography; Severity of valve function Chest radiograph; CTR	7	3	7	3	8	2
d177	Making decisions	-	8	3	-	-	-	-
d230	Carrying out daily routine	-	8	2	-	-	-	-
d310	Communicating with-receiving-spoken messages	FIM; Comprehension	8	2	8	1	8	1
d330	Speaking	FIM; Expression	8	2	8	1	8	2
d420	Transferring oneself	FIM; Transfers	8	1	8	1	8	1
d450	Walking	FIM; Walk 5-m walk test	8	1	8	2	8	5
d510	Washing oneself	FIM; Bathing	8	1	8	1	8	1
d520	Caring for body parts	FIM; Grooming	7	1	8	2	7	1
d530	Toileting	FIM; Toileting	7	2	9	2	7	3
d540	Dressing	FIM; Dressing	8	1	8	1	8	1
d550/ d560	Eating/ Drinking	FIM; Eating	8	1	8	2	8	3
d570	Looking after one's health	-	8	3	-	-	-	-
d620	Acquisition of goods and services	Instrumental Activities of Daily Living scale; Shopping	8	4	8	3	8	3
d630	Preparing meals	Instrumental Activities of Daily Living scale; Food preparation	8	2	8	1	8	3
d640	Doing housework	Instrumental Activities of Daily Living scale; Housekeeping	8	4	8	3	8	3
d710	Basic interpersonal interactions	-	8	3	-	-	-	-
d760	Family relationships	-	8	3	-	-	-	-
d920	Recreation and leisure	-	8	2	-	-	-	-
e310	Immediate family	-	8	3	-	-	-	-
e340	Personal care providers and personal assistants	-	8	2	-	-	-	-
e355	Health professionals	-	8	1	-	-	-	-
e410	Individual attitudes of immediate	-	8	2	-	-	-	-

	family members							
e575	General social support services, systems, and policies	-	8	2	-	-	-	-
d580	Health services, systems, and policies	-	8	3	-	-	-	-

SpO2, oxygen saturation; NYHA, New York Heart Association; CTR, cardiothoracic ratio; FIM, Functional Independence Measure.

DISCUSSION

We have developed a comprehensive assessment for older people with HF based on ICF for widespread use in clinical practice and verified the appropriateness of the scoring method using the RAND Delphi method. In this study, we drew on our literature review and the ICF Reference Guide to link existing assessment batteries for 28 of the 43 ICF categories. In the first Delphi round, 'agreement' was not reached on six questions in the four ICF categories, and the explanation and scoring methods were modified. In the second round of Delphi, all question items of the 43 ICF category were reached to a consensus of 'Appropriate' and 'Agreement'.

The purpose of this study was to develop an assessment method that could be used not only by cardiovascular physicians but also by medical professionals: home physicians, care managers, and paramedical professions. Therefore, we adopted a simple evaluation method that requires as little special machinery and environment as possible. For example, although exercise tolerance at b455 has been reported to be a prognostic factor for HF [49], we avoided the cardiopulmonary exercise testing (CPX) and 6-minute walk test, and the specific activity scale (SAS) was chosen instead. [50-54] We selected gait speed and FIM as the existing assessment batteries linked to the d450 walking, but we selected only FIM for simplicity and ease of assessment at the suggestion of the panel members in the second Delphi round. The ICF categories in this study did not include renal function, BNP or anaemia, which are prognostic factors for heart failure.[55] We suggest that these items be added, although the increase in the items may prevent their wide-spread use in the clinical setting, making their clinical use more difficult. In addition, the comprehensive ICF-based assessment of older patients with HF developed in this study did not include personal factors such as age, gender, values, lifestyle, coping strategies and personality.

In recent years, patient-centred interventions have become a principle in the care of chronic diseases [56]. The ESC guidelines similarly recommend patient-centred care

[57].

We propose that when using the ICF to share information on older people with HF across multiple professions, it is necessary to include not only the 43 ICF categories, but also personal factors.

In Japan, the establishment of a comprehensive community care system that integrates medical care, welfare, and nursing care is being promoted, but evidence for information sharing is lacking. We expect that the ICF-based assessment method for older patients with HF developed in this study will be widely used in clinical practice.

Strengths and limitations

Since the purpose of this study was to develop a common community-based evaluation method for medical and nursing care, we constructed an expert panel related to medical professions and nursing care professions in Hiroshima prefecture. Since there is no variation in the regions of the panel members, the existence of selective bias cannot be denied. Therefore, we suggest that the results of this study should be used with caution in regions other than Hiroshima prefecture. This study was based on the RAND/UCLS Delphi method, but face-to-face meetings could not be conducted because of the current coronavirus pandemic. Therefore, the implementation is not strictly based on the RAND/UCLS method. We believe that we should have held an online meeting during the Delphi Round 2. In this study, the Delphi method through expert consensus was used to clarify the appropriateness of the evaluation method. The shortcomings of the Delphi method are the possibility of coercion and inducement to gather opinions and the issue of the validity of the questionnaire. In the future, it will be necessary to clarify the validity of the evaluation method in survey studies of older patients with heart failure.

Implications and Future directions

The results of this study have two implications. First, it is the establishment of a comprehensive assessment method for older patients with HF, which is a social problem in Japan. Comprehensive multidisciplinary assessment is important to prevent rehospitalization for HF, and the ICF-based scoring method developed in this study is expected to prevent rehospitalization. Second, the ICF-based evaluation method allows for an international comparison of the effectiveness of HF treatment and information sharing. Wagner proposes a patient-centred model for chronic disease care that utilises local social resources and information sharing systems such as information and communication technology (ICT). [58,59] In the future, it is necessary to establish an information sharing system using a comprehensive assessment method based on the

ICF, and to examine the effect of readmission prevention and differences in life function according to local policies.

CONCLUSION

We developed a scoring method based on the ICF for older patients with HF and clarified its appropriateness using the RAND/UCLA Delphi method. Future work is required to develop an ICF-based information sharing system and to clarify its impact on the prevention of re-hospitalisation and quality of life in older patients with HF.

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Contributions

All authors meet the criteria for authorship of the ICMJE. SS, TK, TH and HK contributed to the conceptualisation of the study. SS, NG, HF, SN, YT, NM, KK, MN and MY were responsible for designing the questionnaire and collecting and analysing the data. MN, MY, MM, HO and YY were responsible for recruiting the study participants. YN, YK and HK were responsible for interpreting the results and managing the project. SS and HK supervised all research activities. All authors reviewed the current draft and approved the final current submission.

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Competing interests

The authors declare that there are no conflicts of interest regarding the publication of

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Ethics approval

The study was approved by the Hiroshima University of Epidemiological Research Ethics Review Board (approval number: E-2217).

Provenance and peer review

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Data availability statement

Data are available upon reasonable request.

ORCID iD

Shigehito Shota https://orcid.org/0000-0001-7186-2327

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632 **Figure Legends**

633 Fig. 1: Development of Questionnaire and Delphi process flow

634

635 Fig. 2: Selection of records and process flow diagrams

636

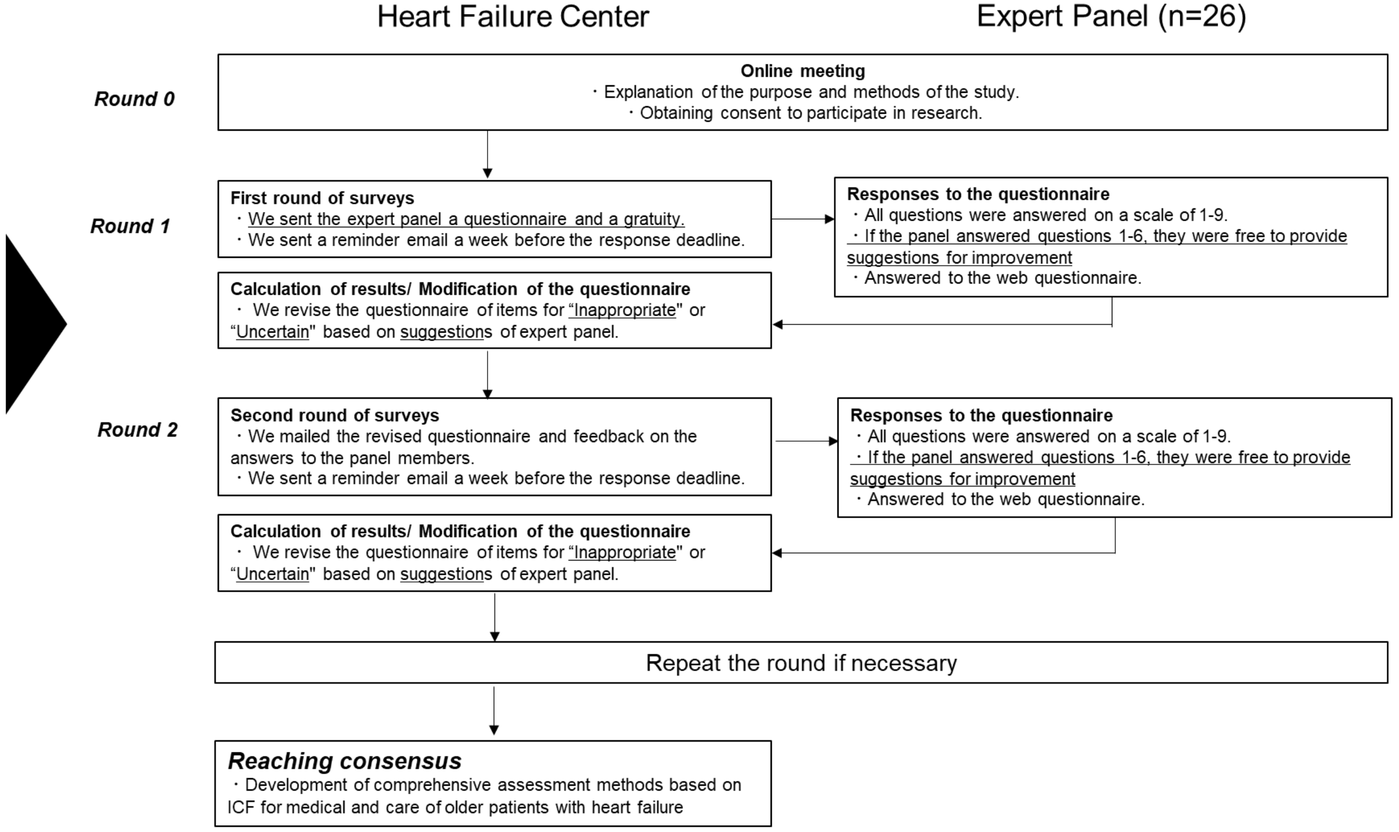
Development of the questionnaire

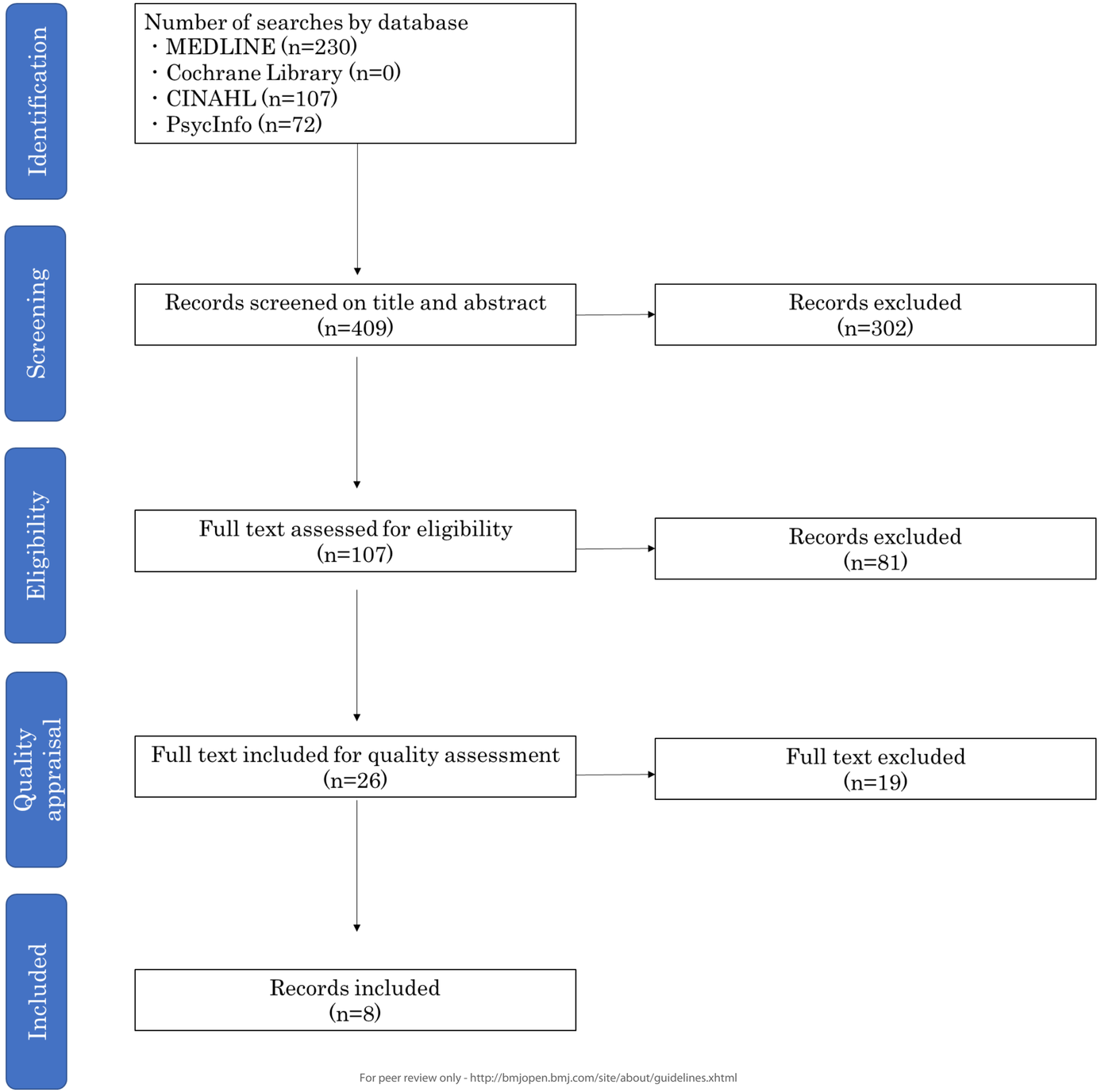
Selection of ICF categories for comprehensive assessment in medical and care of older patients with heart failure: Our previous research
・The Delphi survey among registered instructors of cardiac rehabilitation [34]
・The survey of necessary for care planning for care managers in Japan [35]
・We selected 43 ICF categories for a comprehensive assessment of older people with heart failure.

Literature review: ICF linking rules
We conducted a scoping review of ICF linking rules for the comprehensive assessment of older people with heart failure (43 ICF categories).

Development of the questionnaire:
Appropriateness of the description and scoring methods of the ICF-based assessment for older people with heart failure
Questionnaire items: Responses were obtained on a 1-9 Likert scale. (1: very inappropriate – 9: very appropriate)
1) Appropriateness of ICF 43 category scoring descriptions.
2) Appropriateness of existing assessment batteries linked to each ICF categories.
3) Appropriateness of the scoring methods for each ICF categories linked to existing assessment batteries.

Delphi approach




Identification
Screening
Eligibility
Quality appraisal
Included
Number of searches by database
・MEDLINE (n=230)
・Cochrane Library (n=0)
・CINAHL (n=107)
・PsycInfo (n=72)
Records screened on title and abstract (n=409)
Records excluded (n=302)
Full text assessed for eligibility (n=107)
Records excluded (n=81)
Full text included for quality assessment (n=26)
Full text excluded (n=19)
Records included (n=8)

Supplemental materials 1

Questionnaire

"For each ICF category, please indicate on a scale of 1 (very inappropriate) to 9 (very appropriate) the appropriateness of the following three questions.

(1-3: not appropriate, 4-6: undecided, 7-9: appropriate)"

Questionnaire items

1) Appropriateness of ICF 43 category scoring descriptions.

2) Appropriateness of existing assessment batteries linked to each ICF categories.

3) Appropriateness of the scoring methods for each ICF categories linked to existing assessment.

b110: Consciousness function

General mental functions of the state of awareness and alertness, including the clarity and continuity of the wakeful state.

Inclusions: functions of the state, continuity, and quality of consciousness; loss of consciousness; coma, vegetative states, fugues, trance states, possession states, drug-induced altered consciousness, delirium, stupor

*Exclusions: orientation functions (**b114**); energy and drive functions (**b130**); sleep functions (**b134**)*

1) Appropriateness of b110: consciousness function scoring descriptions.

Ratings

0 No problem

1 Mild problem: May include problems with consciousness functions that do not affect the patient's daily activities.

2 Moderate problem: May include a problem with consciousness functions that exceeds 1, but remains a relatively minor problem (<50%).

3 Severe problem: May include a major problem (≧50%) in consciousness functions.

4 Complete problem: May include a complete problem with consciousness functions, such as coma.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

2) Appropriateness of existing assessment batteries linked to b110: consciousness function

Existing assessment battery linked to b110 consciousness function: Japan Coma Scale

Japan Coma Scale

JCS0 (alert)

JCS Ⅰ (not fully alert but awake without any stimuli)

1: Almost clear consciousness, but not clear.

2: Disorientation (not knowing places, times or dates)

3: Cannot say his/her name or date of birth

JCS Ⅱ (arousable with stimulation)

10: Easy eye-opening with a normal call.

20: Eyes open with loud voice or body shaking

30: Eyes open by repeated calls with pain stimulus.

JCSⅢ(unarousable)

100: Movement to repel the pain stimulus.

200: Slight limb movement or frowning in response to the pain stimulus

300: Does not respond to pain stimulus

[Reference]

1. Ohta T, Waga S, Handa W, et al. New grading of level of disordered consiousness (author's transl). No shinkei geka. Neurol Surg 1974;2:623–7.

2. Ohta T, Kikuchi H, Hashi K, et al. Nizofenone administration in the acute stage following subarachnoid hemorrhage. Results of a multi-center controlled double-blind clinical study. J Neurosurg 1986;64:420–6.

3. Shigemori M, Abe T, Aruga T, et al. Guidelines for the Management of Severe Head Injury, 2nd edition guidelines from the Guidelines Committee on the Management of Severe Head Injury, the Japan Society of Neurotraumatology. Neurol Med Chir 2012;52:1–30

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

3) Appropriateness of the scoring methods for b110 consciousness function linked to Japan Coma Scale.

Ratings

0 No problem: JCS 0

1 Mild problem: JCSⅠ-1 ～ JCSⅠ-3

2 Moderate problem: JCSⅡ-10 ～ JCSⅡ-30

3 Severe problem: JCSⅢ-100 ～ JCSⅢ-200

4 Complete problem: JCSⅢ-300

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

b114: Orientation functions

General mental functions of knowing and ascertaining one's relation to time, to place, to self, to others, to objects, and to space.

Inclusions: functions of orientation to time, place and person; orientation to self and others; disorientation to time, place, and person

Exclusions: consciousness functions (b110); attention functions (b140); memory functions (b144)

1) Appropriateness of b114: Orientation functions scoring descriptions.

Ratings

0 No problem

1 Mild problem: May include problems with orientation functions that do not affect the patient's daily activities.

2 Moderate problem: May include a problem with orientation functions that exceeds 1, but remains a relatively minor problem (<50%).

3 Severe problem: May include a major problem (≧50%) in orientation functions.

4 Complete problem: May include a complete problem with orientation functions.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

2) Appropriateness of existing assessment batteries linked to b114: Orientation functions

Existing assessment battery linked to b114: Orientation functions: Mini-Mental State Examination

Mini-Mental State Examination

Orientation: time

Year, Month, Day, Date, Time: ___/5

Orientation: place

Country, Town, District, Hospital, Ward: ___/5

[Reference]

1. Folstein MF, Folstein SE, McHugh PR. Mini-mental state. A practical method for grading the cognitive state of patients for the clinician. J. Psychiatry Res. 1975; 12: 189–198.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

3) Appropriateness of the scoring methods for b114: Orientation functions linked to Mini-Mental State Examination

Ratings

0 No problem: MMSE; orientation score 5 (Adopt low scores of time or place)

1 Mild problem: MMSE; orientation score 4 (Adopt low scores of time or place)

2 Moderate problem: MMSE; orientation score 3 (Adopt low scores of time or place)

3 Severe problem: MMSE; orientation score 2 (Adopt low scores of time or place)

4 Complete problem: MMSE; orientation score 1-0 (Adopt low scores of time or place)

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

[Reference]

Vriendt PD, Gorus E, Bautmans I, et al. Conversion of the Mini-Mental State Examination to the International Classification of Functioning, Disability and Health terminology and scoring system. Gerontology. 2012;58(2):112-9. doi: 10.1159/000330088.

b130 Energy and drive functions (Mental functions that cause self-driven activities in daily life.**)**

General mental functions of physiological and psychological mechanisms that cause the individual to move towards satisfy specific needs and general goals in a persistent manner.

Inclusions: functions of energy level, motivation, appetites, craving (including craving for substances that can be abused), and impulse control

Exclusions: consciousness functions (b110); temperament and personality functions (b126); sleep functions (b134); psychomotor functions (b147); emotional functions (b152)

1) Appropriateness of b130 Energy and drive functions.

Ratings

0 No problem

1 Mild problem: May include problems with energy and drive functions that do not affect the patient's daily activities.

2 Moderate problem: May include a problem with energy and drive functions that exceeds 1, but remains a relatively minor problem (<50%).

3 Severe problem: May include a major problem (≧50%) in energy and drive functions.

4 Complete problem: May include a complete problem with energy and drive functions, such as having no motivation or appetite any time.

Answer: Please tick the number that best applies

Very inappropriate							Very appropriate	
1	2	3	4	5	6	7	8	9

2) Appropriateness of existing assessment batteries linked to b130 Energy and drive functions

Existing assessment battery linked to b130 Energy and drive functions: Vitality Index

Vitality Index

1. Wake up	
Always waking up on time.	2
Sometimes they don't wake up unless you wake them up.	1
They never wake up on their own.	0
2. Communication	
Greet and talk to them yourself.	2
Responding to greetings and calls for help and smiles are observed.	1

No response.	0
3. Feeding	
Willing to eat on their own initiative	2
Attempts to eat when prompted	1
Lack of interest in eating, unwilling to eat at all	0
4. On and Off Toilet	
Always communicate bowel movements and urination on their own, or urinate and defecate on their own	2
Occasional urinary and bowel movements.	1
No interest in excretion at all.	0
5. Rehabilitation, Activity	
Go to rehabilitation on their own and seek out activities.	2
Participate in rehabilitation and activities when prompted	1
Rejection, indifference.	0
Total	/10

[Reference]

1. Kenji Toba, Ryuhei Nakai, Masahiro Akishita et al: Vitality Index as a useful tool to assess elderly with dementia. Geriatr Gerontol Int 2002; 2: 23-9.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

3) Appropriateness of the scoring methods for b130 Energy and drive functions linked to Vitality Index

Ratings

0 No problem: Vitality Index; Total 10

1 Mild problem: Vitality Index; Total 9-7

2 Moderate problem: Vitality Index; Total 6-4

3 Severe problem: Vitality Index; Total 3-1

4 Complete problem: Vitality Index; Total 0

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

b134 Sleep functions (Extent and frequency of the problem, such as shortage of sleep or irregular sleep schedules**)**

General mental functions of periodic, reversible and selective physical and mental disengagement from one's immediate environment accompanied by characteristic physiological changes.

Exclusions: Attention functions (b140), Consciousness functions (b110), Energy and drive functions (b130), Psychomotor functions (b147)

1) Appropriateness of b134 Sleep functions.

Ratings

0 No problem

1 Mild problem: May include problems with sleep that do not affect the patient's daily activities.

2 Moderate problem: May include a problem with sleep that exceeds 1, but remains a relatively minor problem (<50%).

3 Severe problem: May include a major problem (≧50%) in sleep.

4 Complete problem: May include a complete problem with sleep, such as being incapable of sleeping, or a complete day–night reversal every day.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

2) Appropriateness of existing assessment batteries linked to b134 Sleep functions.

Existing assessment battery linked to b134 Sleep functions: Pittsburgh Sleep Quality Index

Prepared with reference to the Pittsburgh Sleep Quality Index.

1. Amount of sleep: During the past month, how hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed)	
Over 7 hours	0
6-7 hours	1
5-6 hours	2
Less than 5 hours	3
2. Onset of sleep: During the past month, how often have you had trouble sleeping because you cannot get to sleep within 30 minutes	

Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3
3. Maintenance of sleep: During the past month, how often have you had trouble sleeping because you wake up in the middle of the night or early morning	
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3
4. Quality of sleep: During the past month, how would you rate your sleep quality overall?	
Very good	0
Fairly good	1
Fairly bad	2
Very bad	3

[Reference]

1. Buysse DJ, Reynolds CF, Charles F, et al (1989). The Pittsburgh sleep quality index: a new instrument for psychiatric practice and research. Psychiatry Research, 28 (2), 193–213.

2. Doi Y, Minowa M, Uchiyama M, et al. Psychometric assessment of subjective sleep quality using the Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J) in psychiatric disordered and control subjects. Psychiatry Res. 2000 Dec 27;97(2-3):165-72. doi: 10.1016/s0165-1781(00)00232-8.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

3) Appropriateness of the scoring methods for b134 Sleep functions linked to Pittsburgh Sleep Quality Index

Ratings

0 No problem: All items scored 0.

1 Mild problem: Lowest item scores 1

2 Moderate problem: Lowest item scores 2

3 Severe problem: Lowest item scores 3

4 Complete problem: Lowest item scores 1 and use of sleeping pills does not improve the problem

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

b164 Higher-level cognitive functions

Specific mental functions especially dependent on the frontal lobes of the brain, including complex goal-directed behaviours such as decision-making, abstract thinking, planning and carrying out plans, mental flexibility, and deciding which behaviours are appropriate under what circumstances; often called executive functions.

Inclusions: categorization, concept formation, cognitive flexibility

Exclusions: Calculation functions (b172), Memory functions (b144), Mental functions of language (b167), Thought functions (b160)

1) Appropriateness of b164 Higher-level cognitive functions.

Ratings

0 No problem

1 Mild problem: May include problems with **higher-level cognitive functions** that do not affect the patient's daily activities.

2 Moderate problem: May include a problem with **higher-level cognitive functions** that exceeds 1, but remains a relatively minor problem (<50%).

3 Severe problem: May include a major problem (≧50%) in **higher-level cognitive functions**.

4 Complete problem: May include a complete problem with **higher-level cognitive functions.**

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

2) Appropriateness of existing assessment batteries linked to b164 Higher-level cognitive functions.

Existing assessment battery linked to b164 Higher-level cognitive functions: Frontal Assessment Battery

Frontal Assessment Battery

[Reference]

1. Dubois B, Slachevsky A, Litvan I, et al. The FAB: a Frontal Assessment Battery at bedside. Neurology. 2000 Dec 12;55(11):1621-6. doi: 10.1212/wnl.55.11.1621.

2. Nakaaki S, Murata Y, Sato J, et al. Reliability and validity of the Japanese version of the

Frontal Assessment Battery in patients with the frontal variant of frontotemporal dementia. Psychiatry Clin Neurosci. 2007 Feb;61(1):78-83. doi: 10.1111/j.1440-1819.2007.01614.x.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

3) Appropriateness of the scoring methods for b164 Higher-level cognitive functions linked to Frontal Assessment Battery

Ratings

0 No problem: FAB Total scores18-16

1 Mild problem: FAB Total scores15-14

2 Moderate problem: FAB Total scores13-9

3 Severe problem: FAB Total scores8-5

4 Complete problem: FAB Total scores4-0

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

This is followed by questions on b410: Heart function, b415: Blood vessel function and others and a total of 43 ICF categories.

Supplemental material 2

Results of the literature review of the ICF linking Rules: correspondence table of 43 ICF categories and linked existing assessment batteries.

Study	Darzins SW, et al (2017) [46]	Milman N, et al (2015) [42]	Hoang-Kim A, et al (2013). [43]		Cieza A, et al (2005). [44]					Prodinger B, et al (2019) [47]		Alarcos Cieza (2008) [45]	Bladh S, et al (2013) [41]				Prodinger B, et al (2017) [40]	
Assessment batteries	**FIM**	**SF-36**	**EQ-5D**	**SF-36**	**EQ-5D**	**SF-36**	**NHP**	**WHODAS 2.0**	**WHOQOL-CHEF**	**WHODAS 2.0**	**SF-36**	**SF-36**	**FES-I**	**FES(S)**	**ABC**	**SAFFE**	**FIM**	**Birthel Index**
b110																		
b114																		
b130		✔		✔			✔		✔			✔						
b134							✔		✔									
b164																		
b410																		
b415																		
b420																		
b440																		
b455																		
b460																		
b525	✔																	
b530																		
b540																		
b620	✔																	
b710																		
b730																		
s410																		

d177																		
d230				✔	✔	✔		✔	✔									
d310								✔										
d330																		
d420				✔						✔								
d450	✔		✔	✔	✔	✔	✔						✔		✔	✔	✔	✔
d510	✔		✔	✔	✔	✔		✔		✔			✔	✔		✔		✔
d520	✔									✔								
d530	✔									✔				✔			✔	✔
d540	✔		✔	✔	✔	✔	✔	✔					✔	✔			✔	✔
d550	✔							✔										✔
d560	✔																	
d570																✔		
d620										✔			✔	✔		✔		
d630							✔			✔			✔			✔		
d640			✔	✔				✔					✔	✔	✔	✔		
d710																		
d760			✔	✔	✔													
d920			✔	✔	✔	✔	✔	✔	✔				✔			✔		
e310																		
e340																		
e355																		
e410																		
e575																		
e580									✔									

Functional Independence Measure (FIM), Short-Form 36 health survey (SF-36), EuroQol 5 dimensions (EQ-5D), the Nottingham Health Profile(NHP), the World Health Organization Disability Assessment Schedule (WHODAS 2.0), the World Health Organization Quality of Life Assessment (WHOQOL-BREF)

Falls Efficacy Scale-International (FES-I), the Swedish version of the Falls Efficacy Scale (FES[S]), the Activities-specific Balance Confidence Scale (ABC), the modified Survey of Activities and Fear of Falling in the Elderly (SAFFE)

Supplemental material 3

Results of the three questions of the 43 ICF categories in the first Delphi round

ICF categories		Existing assessment batteries linked to ICF categories	Question Items					
			1) Appropriateness of ICF 43 category scoring descriptions		2) Appropriateness of existing assessment batteries linked to each ICF categories		3) Appropriateness of the scoring methods for each ICF categories linked to existing assessment batteries	
			median score (/9)	Number of outside median tertile (/21)	median score (/9)	Number of outside median tertile (/21)	median score (/9)	Number of outside median tertile (/21)
b110	Consciousness function	Japan Coma Scale	7	7	8	1	7	4
b114	Orientation function	Mimi-Mental State Examination	8	6	8	2	8	4
b130	Energy and drive function	Vitality Index	7	7	8	2	8	2
b134	Sleep function	-	**7**	**9**	-	-	-	-
b164	Higher-level cognitive functions	Frontal Assessment Battery	7	6	7	7	7.5	4
b410	Heart function	Echocardiography; left ventricular function, Electrocardiogram	7	4	**7**	**8**	**7**	**11**
b415	Blood vessel function	Fontaine classification	7	5	8	2	8	4
b420	Blood pressure function	Blood pressure	7	6	7.5	4	8	4
b440	Respiration function	Arterial Blood Gas Analysis, fraction of inspiratory oxygen, SpO_2, Respiration Rate	8	4	8	4	7	5
b455	Exercise tolerance function	Specific Activity Scale	8	3	7.5	1	7	3
b460	Sensations associated with cardiovascular and respiratory functions	NYHA classification	8	4	8	3	8	2
b525	Defaecation function	-	7	6	7	4	-	-
b530	Weight maintenance functions	Body Mass Index	7	6	8	3	8	4
b545	Water, mineral and electrolyte balance functions	Blood test: Na, K	7.5	5	8	4	7.5	6

b620	Urination function	-	7	5	8	2	-	-
b710	Mobility of joint function	Range Of Motion	8	4	7	4	7	5
b730	Muscle power function	Manual Muscle Test or five-times sit-to-stand	8	4	7.5	5	7.5	6
s410	Structure of the cardiovascular system	Echocardiography; Severity of valve function Chest radiograph; CTR	7	5	**7**	**9**	**7**	**9**
d177	Making decisions	-	8	3	-	-	-	-
d230	Carrying out daily routine	-	8	2	-	-	-	-
d310	Communicating with-receiving-spoken messages	FIM; Comprehension	7.5	5	8	4	8	4
d330	Speaking	FIM; Expression	8	5	**7**	**8**	7	7
d420	Transferring oneself	FIM; Transfers	8	3	8	0	8	2
d450	Walking	FIM; Walk 5-m walk test	8	4	7	5	7	5
d510	Washing oneself	FIM; Bathing	8	3	8	4	7	4
d520	Caring for body parts	FIM; Grooming	8	4	7.5	2	7	4
d530	Toileting	FIM; Toileting	7	4	8	1	8	4
d540	Dressing	FIM; Dressing	8	4	7.5	2	7	4
d550/ d560	Eating/ Drinking	FIM; Eating	8	4	8	3	8	5
d570	Looking after one's health	-	7.5	3	-	-	-	-
d620	Acquisition of goods and services	Instrumental Activities of Daily Living scale; Shopping	7.5	4	8	4	7	5
d630	Preparing meals	Instrumental Activities of Daily Living scale; Food preparation	7	7	7.5	3	7	6
d640	Doing housework	Instrumental Activities of Daily Living scale; Housekeeping	7	5	7	2	7	4
d710	Basic interpersonal interactions	-	8	2	-	-	-	-
d760	Family relationships	-	8	3	-	-	-	-
d920	Recreation and leisure	-	8	4	-	-	-	-
e310	Immediate family	-	8	4	-	-	-	-
e340	Personal care providers and personal assistants	-	7	4	-	-	-	-
e355	Health professionals	-	8	4	-	-	-	-

e410	Individual attitudes of immediate family members	-	7.5	5	-	-	-	-
e575	General social support services, systems, and policies	-	7.5	5	-	-	-	-
e580	Health services, systems, and policies	-	7.5	3	-	-	-	-

SpO2, oxygen saturation; NYHA, New York Heart Association; CTR, cardiothoracic ratio; FIM, Functional Independence Measure.

Bolded text indicates items of disagreement.

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Complete List of Authors:	Shiota, Shigehito; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Hospital, Department of Rehabilitation Kitagawa, Toshiro; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Graduate School of Biomedical and Health Sciences , Department of Cardiovascular medicine Goto, Naoya; Hiroshima University Hospital, Department of Rehabilitation Fujisita, Hironori; Hiroshima University Hospital, Department of Rehabilitation Tamekuni, Yurika; Hiroshima University Hospital, Department of Rehabilitation Nakayama, Susumu; Home nursing station Sakurazaka Mio, Naoki; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Hospital, Department of Rehabilitation Kanai, Kana; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Hospital, Department of Rehabilitation Naka, Makiko; Hiroshima University Hospital, Heart Failure Center Yamaguchi, Mizuho; Hiroshima University Hospital, Heart Failure Center Mochizuki, Mariko; Hiroshima Care Manager Association Ochikubo, Hiroyuki; Hiroshima Care Manager Association Hidaka, Takayuki; Hiroshima Prefectural Hospital, Department of Cardiovascular Medicine Yasunobu, Yuji; Miyoshi Medical Association Hospital, Department of Cardiovascular Medicine Nakano, Yukiko; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Graduate School of Biomedical and Health Sciences, Department of Cardiovascular medicine Kihara, Yasuki; Hiroshima University Graduate School of Biomedical and Health Sciences Kimura, Hiroaki; Hiroshima University Hospital, Heart Failure Center; Hiroshima University Hospital, Department of Rehabilitation Medicine
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Original research

Development and appropriateness of a scoring method for International Classification of Functioning, Disabilities, and Health assessment in older patients with heart failure: a Delphi survey of expert panel in Japan

Shigehito Shiota[1,2], Toshiro Kitagawa[1,3], Naoya Goto[2], Hironori Fujisita[2], Yurika Tamekuni[2], Susumu Nakayama[4], Naoki Mio[1,2], Kana Kanai[1,2], Makiko Naka[1], Mizuho Yamaguchi[1], Mariko Mochizuki[5], Hiroyuki Ochikubo[5], Takayuki Hidaka[6], Yuji Yasunobu[7], Yukiko Nakano[1,3], Yasuki Kihara [8], Hiroaki Kimura[1,9]

[1] Heart Failure Centre, Hiroshima University Hospital, Hiroshima, Japan

[2] Division of Clinical Support, Department of Rehabilitation, Hiroshima University Hospital, Hiroshima, Japan

[3] Hiroshima University Graduate School of Biomedical and Health Sciences, Hiroshima, Japan

[4] Home nursing station Sakurazaka, Hiroshima, Japan

[5] Hiroshima Care Manager Association, Hiroshima, Japan.

[6] Department of Cardiovascular Medicine, Hiroshima Prefectural Hospital, Hiroshima, Japan

[7] Department of Cardiovascular Medicine, Miyoshi Medical Association Hospital, Hiroshima, Japan

[8] Hiroshima University Graduate School of Biomedical and Health Sciences, Hiroshima, Japan

[9] Department of Rehabilitation Medicine, Hiroshima University Hospital, Hiroshima, Japan

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Corresponding author:

Shigehito Shiota

Email: sshiota@hiroshima-u.ac.jp

Address: 1-2-3, Kasumi, Minami-ku, Hiroshima City, Hiroshima, Japan

ABSTRACT

Objective: The number of older patients with heart failure (HF) is increasing in Japan and has become a social problem. There is an urgent need to develop a comprehensive assessment methodology based on the common language of health care; the International Classification of Functioning, Disability and Health (ICF). The purpose of this study was to develop and confirm the appropriateness of a scoring methodology for 43 ICF categories in older people with HF.

Design: Cross-sectional survey. We applied the RAND/UCLA Appropriateness Method with a modified Delphi method.

Setting and participants: We included a panel of 26 multidisciplinary experts on HF care consisting of home physicians, cardiovascular physicians, care managers, nurses, physical therapists, a pharmacist, occupational therapist, nutritionist, and a social worker.

Measures: We conducted a literature review of ICF linking rules and developed a questionnaire on scoring methods linked to ICF categories in older people with HF. In the Delphi rounds, we sent the expert panel a questionnaire consisting of three questions for each of the 43 ICF categories. The expert panel responded to the questionnaire items on a 1 (very inappropriate) – 9 (very appropriate) Likert scale and repeated rounds until a consensus of 'Appropriate' and 'Agreement' was reached on all items.

Results: A total of 21 panel members responded to all the Delphi rounds. In the first Delphi round, six question items in four ICF categories did not reach a consensus of 'Agreement', but the result of our modifications based on panel members' suggestions reached to a consensus of 'Appropriate' and 'Agreement' on all questions in the second Delphi round.

Conclusion: The ICF-based scoring method for older people with HF developed in this study was found to be appropriate. Future work is needed to clarify whether comprehensive assessment and information sharing based on ICF contributes to preventing readmissions.

Keywords: heart failure, older people, ICF, scoring methods, RAND/UCLA Appropriateness Method

Strengths and limitations of this study

►An expert panel familiar with heart failure care, consisting of home physicians, care managers, and multidisciplinary medical professionals, rated the "appropriateness" of the questions in each ICF category through a multiple-round process to reach a consensus.

► The assessment domains studied the 43-item ICF relevant to older adults with heart failure, covering not only the medical assessment but also the physical and mental functioning, activity and social participation, and environmental factors.

►The expert panel comprised general practitioners, cardiologists, and paramedical professions (rehabilitation, nursing care, and welfare), but caution is needed in generalizing the findings because of the study's limited geographical area.

INTRODUCTION

In Japan, cardiovascular disease is the second leading cause of death. [1] In addition, cardiovascular disease accounts for 20.6% of all cases requiring nursing care, and the annual medical costs exceed 6 trillion yen (USD 46 billion). [2,3] The Japanese government has approved the Japanese National Plan for Promotion of Measures Against Cerebrovascular and Cardiovascular Disease in 2020. This Japanese National Plan promotes the establishment of a comprehensive community care system that encompasses health, medical care, welfare, nursing care, and the sharing of evidence-based information. [4,5]

Among cardiovascular diseases, heart failure (HF) is increasing with the ageing of the population, with the number of patients in Japan expected to exceed 1.3 million by 2030. [6,7] HF reduces the quality of life of patients and their families by repeated rehospitalizations due to exacerbations, and the increased burden of medical expenses. [8-10] The one-year readmission rate for patients with HF is 35% in Japan, but a study of elderly patients with HF in the United States reported a rate of 64%. [11,12] Elderly patients with HF have multiple comorbidities, such as atrial fibrillation, chronic renal failure, dementia, and depression, which are factors associated with readmission. [13] In addition, many factors have been reported to be associated with readmission in patients with HF, including cognitive function, depression/anxiety, exercise tolerance, muscle strength, walking speed, activities of daily living (ADL), and instrumental activities of daily living (IADL). [14-18] The Guideline on Diagnosis and Treatment of Acute and Chronic Heart Failure (JCS 2017/ JHFS 2017) recommends that patients with limited self-care capabilities, such as elderly patients with HF, should receive education and support from their families and actively utilise social resources such as home physicians and home-visit nursing. [19] Social support and information sharing in the community have been reported to prevent HF readmissions, and there is an urgent need to establish an information sharing system between medical professionals and care professionals in the community. [20,21]

The Japanese Society of Heart Failure recommends the use of the International Classification of Functioning, Disability and Health (ICF) for the comprehensive assessment and multidisciplinary information sharing in elderly patients with HF. [22] The ICF was introduced by the WHO in 2001; it aims to provide a framework for health and health-related conditions. The ICF is expected to be used as a common language for patients, their families, medical professionals, and caregivers. [23] However, the ICF has not been widely used in clinical practice because of the complexity of the coding and the unreliability of the scores. [24-28] To promote the use of the ICF in clinical practice, the

World Health Organisation provides the ICF Core Set and the ICF Linking Rules. The ICF Core Set is a set of identified ICF categories for assessing a patient's special health condition or special medical background. [29] The ICF Linking Rules are a method of linking ICF categories with existing assessment methods. [30,31] The ICF core set for chronic ischaemic heart disease and the Geriatric ICF core set have already been developed, but these ICF categories are not appropriate for adaptation to older patients with heart failure. [32,33] Therefore, 43 ICF categories were selected for the comprehensive assessment of older patients with HF through the questionnaire survey of a multidisciplinary group of medical professionals and care professionals. [34,35] The 43 ICF categories specific to older patients with HF consisted of 17 body functions and one body structure, 19 activities and participation, and 6 environmental factors. However, in order to efficiently utilize ICF-based assessments in clinical practice, it is necessary to develop scoring methods linked to existing assessments.

The purpose of this study was to develop a scoring method of older patients with HF based on the ICF, and to determine its appropriateness using the Delphi technique.

METHOD

Patient and public involvement

Patients and the public are not involved in the design, planning, conduct or reporting of this study.

Design

We applied the Delphi method to an expert panel. The Delphi method is a consensus method used in the development of guidelines and clinical indicators, and is effective in guiding assessments and treatments for which there is limited evidence. The Delphi method is also a standard practice in the development of ICF Core Sets. [29] We developed a questionnaire based on the literature review and structured a two-stage Delphi survey with an expert panel, referring to the RAND/UCLA appropriateness methodology. [36] (Figure 1).

Establishing of the expert panel

We established an expert multidisciplinary panel consisting of 26 medical and care professionals in Hiroshima Prefecture, Japan. The members of the expert committee were professionals with leadership roles in community care, all of whom have expertise in the assessment, treatment, and care of older patients with heart failure. Five home physicians and ten care managers were recommended by the Hiroshima Care Manager

Association. All five home physicians are specialists in internal medicine who engage in home visits while all ten care managers are board members of the Hiroshima Care Manager Association and leaders in their respective communities. In addition, we included 11 medical multidisciplinary professionals involved in HF care at specialised medical institutions recommended by the Hiroshima Heart Health Promotion Project in our panel .[37] The 11 medical multidisciplinary members were: two cardiovascular physicians, three nurses certified in chronic HF nursing, two physiotherapists with registered instructors of cardiac rehabilitation, one occupational therapist with registered instructors of cardiac rehabilitation, one certified pharmacist, one nutritionist, and one social worker.

Development of the questionnaire

We developed scoring methods for the 43 ICF categories linking to existing assessment batteries. [34,35] To develop the questionnaire, we first conducted a literature review of the ICF linking rules. The ICF linking rules are a systematic methodology for linking the existing assessment batteries to the ICF codes. [30,31] All articles related to the ICF linking rule from January, 2005 to August, 2020 were included in the study. We used MEDLINE (PubMed), Cochrane Library, CINAHL, and PsycoInfo as electronic article databases. The search terms in the electronic article database were "ICF" and "Linking rule" or "Rasch" in medical subject headings (MeSH). The search criteria were as follows: (1) written in English, (2) cross-sectional study, cohort study, or case-control study, (3) target group of people aged 18 years or older, (4) use of an existing assessment battery, (5) results from ICF data or Rasch analysis of the ICF data, and (6) "ICF" and "linking rule" present in the title. The literature review was carried out by five authors (SS, NG, HF, SN, and YT) in two phases. In the first phase, the appropriateness of the titles and abstracts were assessed based on the search criteria. In the second phase, the full text was assessed. Finally, we conducted a qualitative analysis of the articles to select an assessment battery that could be adapted to older patients with HF and to clarify its association with the 43 ICF categories. We completed the questionnaire based on the results of this literature review and the explanatory notes in the ICF Reference Guide. [38,39] We set three questions for each of the 43 ICF categories and prepared 1 (very inappropriate) - 9 (very appropriate) Likert scale responses to assess appropriateness. Appropriateness was evaluated on a median response scale with the following three levels: 1-3 as “inappropriate”, 4-6 as “uncertain”, and 7-9 as “appropriate”. The three questionnaire items were as follows: 1) Appropriateness of the 43 ICF category scoring descriptions, 2) appropriateness of

existing assessment batteries linked to each ICF categories, and 3) appropriateness of the scoring methods for each ICF categories linked to existing assessment batteries. All questionnaires were developed using a Google Form, with a description of each ICF category and the rationale for scoring. (Supplemental materials 1).

Delphi process and funding consensus

The Delphi process for reaching a consensus is shown in Figure 1. Following the RAND/UCLA appropriateness methodology [28], we used the median scores of the responses from the panellists to assess appropriateness. We rated the appropriateness of the 43 ICF categories as 'Appropriate' if the median respondent's score was from 7–9, 'Uncertain' if it was from 4–6, and 'Inappropriate' if it was from 1–3. In accordance with the RAND/UCLA guidelines, we defined 'Agreement' or 'Disagreement' according to the number of panellists who rated outside the range of the tertiles (1–3; 4–6; 7–9), including the median. 'Agreement' was defined as fewer than one-third of panellists rating outside the range of the tertile values, whereas 'Disagreement' was defined as more than one-third of panellists rating the extremes (1–3 range and 7–9 range), not including the median.

Before conducting the Delphi survey, the HF Centre (HFC) held an online meeting for the panel members. In the online meeting, we explained the purpose of our study and the methods of the Delphi process to the panel members and obtained their consent to participate in the study. In the first round, the HFC mailed a sheet with instructions on how to conduct the ICF category adequacy assessment, as well as the URL and QR codes for the questionnaire. The panel members responded to three questions in 43 ICF categories on a scale of 1-9. In addition, panel members provided open-ended suggestions for improvements to the questions they scored 1-6. The HFC collated the panel members' responses. We revised the scoring descriptions and existing assessment batteries linked to the ICF categories responded to as 'Inappropriate', 'Uncertain' or 'Disagreement' based on the panel's suggestions. In the second round, the HFC emailed the revised questionnaire and feedback based on the panel members' responses. As in the first round, panel members again scored the appropriateness of three of the question items in all 43 ICF categories. In addition, the panel members provided suggestions for improvements to the scoring methods on those ones scored 1-6.

The HFC compiled the panel members' responses and assessed their appropriateness. We also revised the descriptions of the questionnaire or scoring methods based on the panel's suggestions. The revised questionnaire was emailed to the panel members, and

a final consensus was reached after confirming that there were no comments for revision.

Analysis

Data were exported from Google Forms to Microsoft Excel 2019 (Microsoft Washington USA) for descriptive calculations. Data are presented as simple totals and median.

Ethics

This study was conducted in accordance with the principles of the Declaration of Helsinki. We explained the purpose and content of the study in writing and at online meetings to the expert panel members who participated in the study and obtained their written consent. The received data was processed after deleting personal information (names). Approval was obtained from the Ethical Review Committee for Epidemiological Research, Hiroshima University (Approval No: E-2580). This study was supported by the MHLW Comprehensive Research on Statistical Information Program, Grant Number JPMH20AB1002.

RESULTS

Characteristics of the expert panel participants

A total of 26 experts agreed to participate in the study. In the first round, 24 of the 26 invited experts responded to the questionnaire. In the second Delphi round, 21 experts responded to the questionnaires. Table 1 shows the characteristics of the experts who responded to all Delphi rounds.

Table 1 Characteristics of the expert panel participants who responded to all Delphi rounds (n = 21)

Characteristics	n (%)
Sex	
Male	8 (38.1)
Female	13 (61.9)
Professions	
Home physicians	4 (19.0)
Cardiovascular physicians	1 (4.8)
Care managers	9 (42.8)
Nurses	3 (14.3)
Pharmacist	1 (4.8)
Physical therapists	2 (9.5)

Occupational therapist	1 (4.8)
Type of facilities	
Hospital: Acute care ward	6 (28.6)
Hospital: Rehabilitation ward	2 (9.5)
Clinic	4 (19.0)
Regional comprehensive support centre	2 (9.5)
Community care centre/Home nursing station	6 (28.6)
Municipal office	1 (4.8)

Development of the Delphi questionnaire of ICF assessment method for older patients with heart failure

Figure 2 showed the process of literature review. Following a two-stage screening process, we conducted a qualitative analysis of 26 references. In the qualitative analysis, we excluded 19 references dealing with disease-specific assessment batteries that could not be adapted to older patients with HF (e.g., stroke, musculoskeletal disease, hand surgery, low back pain). Eight articles on ICF linking rules were included. Finally, we employed 11 existing assessment batteries on eight articles links to the 43 ICF categories (Supplemental material 2). [40-47] Eleven existing assessment batteries were included: assessment of ADL (such as Functional Independence Measure (FIM) and Barthel Index), assessment of general health-related quality of life (such as Short Form 36 and the European Quality of Life instrument (EQ-5D), The World Health Organization Quality of Life (WHOQOL)), assessment of general health status (such as the Nottingham Health Profile(NHP), the World Health Organization Disability Assessment Schedule (WHODAS 2.0)), and assessment of falls (such as Falls Efficacy Scale-International (FES-I), the Swedish version of the Falls Efficacy Scale (FES[S]), the Activities-specific Balance Confidence Scale (ABC), and the modified Survey of Activities and Fear of Falling in the Elderly (SAFFE)). We identified these existing assessment batteries as linked to 20 of the 43 categories. However, we included only the FIM and the BI. We did not include assessment batteries for general health-related quality of life, general health status, and falls in the questionnaire because these were not consistent with the aims of this study.

Therefore, we developed a scoring methodology for ICF categories other than ADL, based on the Italian ICF Guidelines and the ICF Reference Guide. [38,39,48] Finally, we decided to provide 30 existing assessment batteries linking to ICF categories, and to score the remaining 13 categories using only the scoring descriptions (Table 2).

Delphi round 1

From February to March of 2021, 24 panel members (92.3%) responded to Round 1 of the Delphi process. 'Agreement' was defined as when seven or fewer panellists rated outside the range of the three quartiles (1-3; 4-6; 7-9), including the median. 'Disagreement' was defined as eight or more panellists rating the extremes (1-3 range and 7-9 range) that did not include the median. The results of the Delphi round 1 panel members' responses are shown in Supplementary material 3. The median response of panel members was 'appropriate' 7-9 for all three questions in the 43 ICF categories. In the result, 'Agreement' was not reached on six question items in four ICF categories. The question items in the ICF categories on which agreement was not reached were 'b134 Sleep functions: 1) scoring descriptions, b410 Heart function: 2) existing assessment batteries and 3) scoring methods linked to ICF categories, s410 Structure of the cardiovascular systems: 2) existing assessment battery and 3) scoring methods linked to ICF categories and d330 Speaking: 2) existing battery of assessments'. We added a scoring method for d134 Sleep function based on the Pittsburgh Sleep Quality Index, based on the panel members' suggestions. For b410 heart function, S410 Structure of cardiovascular system and d330 Speaking, we revised the existing assessment battery and scoring method linked to the ICF categories based on the panel's suggestions.

Delphi round 2

From April to May of 2021, we emailed the revised questionnaire to the 24 panel members who responded to Round 1. Twenty-one panel members (87.5%) responded to the Round 2 questionnaire. 'Agreement' was defined as when six or fewer panellists rated outside the range of the three quartiles (1-3; 4-6; 7-9), including the median. 'Disagreement' was defined as seven or more panellists rating the extremes (1-3 range and 7-9 range) that did not include the median. Table 2 shows the results of the panel members' responses to Delphi Round 2. The results showed that for all ICF category questions, the median responses ranged from 7 to 9 'Appropriate', with all items reaching 'Agreement'. However, as two panel members answered 'Inappropriate' 1-3 for the d450 gait, we modified the existing assessment battery linked to the ICF categories to FIM only, based on members' suggestions. We sent the manual of the modified assessment method by e-mail to all panel members who participated in Round 2, asking for their comments, and confirming that we had reached a consensus.

Table 2: Results of the three questions of the 43 ICF categories in the second Delphi

310 round.

ICF categories		Existing assessment batteries linked to ICF categories	Question Items					
			1) Appropriateness of ICF 43 category scoring descriptions		2) Appropriateness of existing assessment batteries linked to each ICF categories		3) Appropriateness of the scoring methods for each ICF categories linked to existing assessment batteries	
			median score (/9)	Number of outside median tertile (/21)	median score (/9)	Number of outside median tertile (/21)	median score (/9)	Number of outside median tertile (/21)
b110	Consciousness function	Japan Coma Scale	8	3	9	2	8	1
b114	Orientation function	Mimi-Mental State Examination	8	3	8	4	8	2
b130	Energy and drive function	Vitality Index	8	2	8	3	8	2
b134	Sleep function	Pittsburgh Sleep Quality Index	8	2	8	2	7	4
b164	Higher-level cognitive functions	Frontal Assessment Battery	8	2	8	2	8	3
b410	Heart function	Echocardiography; left ventricular function, Electrocardiogram	7	4	8	3	7	3
b415	Blood vessel function	Fontaine classification	8	4	8	2	8	4
b420	Blood pressure function	Blood pressure	8	4	8	1	8	2
b440	Respiration function	SpO_2, Respiration Rate	8	2	8	3	8	1
b455	Exercise tolerance function	Specific Activity Scale	8	2	8	3	8	1
b460	Sensations associated with cardiovascular and respiratory functions	NYHA classification	8	2	8	1	9	1
b525	Defaecation function	-	8	3	-	-	-	-
b530	Weight maintenance functions	Body Mass Index	8	3	8	3	8	3
b545	Water, mineral and electrolyte balance functions	Blood test: Na, K	8	4	8	3	7	3
b620	Urination function	-	8	4	-	-	-	-
b710	Mobility of joint function	Range Of Motion	8	3	8	3	8	2
b730	Muscle power function	Manual Muscle Test or five-times	8	3	8	3	8	4

		sit-to-stand						
s410	Structure of the cardiovascular system	Echocardiography; Severity of valve function Chest radiograph; CTR	7	3	7	3	8	2
d177	Making decisions	-	8	3	-	-	-	-
d230	Carrying out daily routine	-	8	2	-	-	-	-
d310	Communicating with-receiving-spoken messages	FIM; Comprehension	8	2	8	1	8	1
d330	Speaking	FIM; Expression	8	2	8	1	8	2
d420	Transferring oneself	FIM; Transfers	8	1	8	1	8	1
d450	Walking	FIM; Walk 5-m walk test	8	1	8	2	8	5
d510	Washing oneself	FIM; Bathing	8	1	8	1	8	1
d520	Caring for body parts	FIM; Grooming	7	1	8	2	7	1
d530	Toileting	FIM; Toileting	7	2	9	2	7	3
d540	Dressing	FIM; Dressing	8	1	8	1	8	1
d550/ d560	Eating/ Drinking	FIM; Eating	8	1	8	2	8	3
d570	Looking after one's health	-	8	3	-	-	-	-
d620	Acquisition of goods and services	Instrumental Activities of Daily Living scale; Shopping	8	4	8	3	8	3
d630	Preparing meals	Instrumental Activities of Daily Living scale; Food preparation	8	2	8	1	8	3
d640	Doing housework	Instrumental Activities of Daily Living scale; Housekeeping	8	4	8	3	8	3
d710	Basic interpersonal interactions	-	8	3	-	-	-	-
d760	Family relationships	-	8	3	-	-	-	-
d920	Recreation and leisure	-	8	2	-	-	-	-
e310	Immediate family	-	8	3	-	-	-	-
e340	Personal care providers and personal assistants	-	8	2	-	-	-	-
e355	Health professionals	-	8	1	-	-	-	-
e410	Individual attitudes of immediate family members	-	8	2	-	-	-	-
e575	General social support services,	-	8	2	-	-	-	-

	systems, and policies							
e580	Health services, systems, and policies	-	8	3	-	-	-	-

SpO2, oxygen saturation; NYHA, New York Heart Association; CTR, cardiothoracic ratio; FIM, Functional Independence Measure.

DISCUSSION

We have developed a comprehensive assessment for older people with HF based on ICF for widespread use in clinical practice and verified the appropriateness of the scoring method using the RAND Delphi method. In this study, we drew on our literature review and the ICF Reference Guide to link existing assessment batteries for 28 of the 43 ICF categories. In the first Delphi round, 'agreement' was not reached on six questions in the four ICF categories, and the explanation and scoring methods were modified. In the second round of Delphi, all question items of the 43 ICF category were reached a consensus of 'Appropriate' and 'Agreement'.

The purpose of this study was to develop an assessment method that could be used not only by cardiovascular physicians but also by medical professionals: home physicians, care managers, and paramedical professions. Therefore, we adopted a simple evaluation method that requires as little special machinery and environment as possible. For example, although exercise tolerance at b455 has been reported to be a prognostic factor for HF [49], we avoided the cardiopulmonary exercise testing (CPX) and 6-minute walk test, and the specific activity scale (SAS) was chosen instead. [50-54] We selected gait speed and FIM as the existing assessment batteries linked to the d450 walking, but we selected only FIM for simplicity and ease of assessment at the suggestion of the panel members in the second Delphi round. The ICF categories in this study did not include renal function, BNP or anaemia, which are prognostic factors for heart failure.[55] We suggest that these items be added, although the increase in the items may prevent their wide-spread use in the clinical setting, making their clinical use more difficult. In addition, the comprehensive ICF-based assessment of older patients with HF developed in this study did not include personal factors such as age, gender, values, lifestyle, coping strategies and personality.

In recent years, patient-centred interventions have become a principle in the care of chronic diseases [56]. The ESC guidelines similarly recommend patient-centred care [57].

We propose that when using the ICF to share information on older people with HF across

multiple professions, it is necessary to include not only the 43 ICF categories, but also personal factors.

In Japan, the establishment of a comprehensive community care system that integrates medical care, welfare, and nursing care is being promoted, but evidence for information sharing is lacking. We expect that the ICF-based assessment method for older patients with HF developed in this study will be widely used in clinical practice.

Strengths and limitations

Since the purpose of this study was to develop a common community-based evaluation method for medical and nursing care, we constructed an expert panel related to medical professions and nursing care professions in Hiroshima prefecture. Since there is no variation in the regions of the panel members, the existence of selective bias cannot be denied. Therefore, we suggest that the results of this study should be used with caution in regions other than Hiroshima prefecture. This study was based on the RAND/UCLA Delphi method, but face-to-face meetings could not be conducted because of the current coronavirus pandemic. Therefore, the implementation is not strictly based on the RAND/UCLS method. We believe that we should have held an online meeting during the Delphi Round 2. In this study, the Delphi method through expert consensus was used to clarify the appropriateness of the evaluation method. The shortcomings of the Delphi method are the possibility of coercion and inducement to gather opinions and the issue of the validity of the questionnaire. In the future, it will be necessary to clarify the validity of the evaluation method in survey studies of older patients with heart failure.

Implications and Future directions

The results of this study have two implications. First, it is the establishment of a comprehensive assessment method for older patients with HF, which is a social problem in Japan. Comprehensive multidisciplinary assessment is important to prevent rehospitalization for HF, and the ICF-based scoring method developed in this study is expected to prevent rehospitalization. Second, the ICF-based evaluation method allows for an international comparison of the effectiveness of HF treatment and information sharing. Wagner proposes a patient-centred model for chronic disease care that utilises local social resources and information sharing systems such as information and communication technology (ICT). [58,59] In the future, it is necessary to establish an information sharing system using a comprehensive assessment method based on the ICF, and to examine the effect of readmission prevention and differences in life function according to local policies.

CONCLUSION

We developed a scoring method based on the ICF for older patients with HF and clarified its appropriateness using the RAND/UCLA Delphi method. Future work is required to develop an ICF-based information sharing system and to clarify its impact on the prevention of re-hospitalisation and quality of life in older patients with HF.

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Contributions

All authors meet the criteria for authorship of the ICMJE. SS, TK, TH and HK contributed to the conceptualisation of the study. SS, NG, HF, SN, YT, NM, KK, MN and MY were responsible for designing the questionnaire and collecting and analysing the data. MN, MY, MM, HO and YY were responsible for recruiting the study participants. YN, YK and HK were responsible for interpreting the results and managing the project. SS and HK supervised all research activities. All authors reviewed the current draft and approved the final current submission.

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Competing interests

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Ethics approval

The study was approved by the Hiroshima University of Epidemiological Research Ethics Review Board (approval number: E-2217).

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Data availability statement

No additional data available.

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ORCID iD

Shigehito Shota https://orcid.org/0000-0001-7186-2327

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630 **Figure Legends**

631 Fig. 1: Development of Questionnaire and Delphi process flow

632

633 Fig. 2: Selection of records and process flow diagrams

634

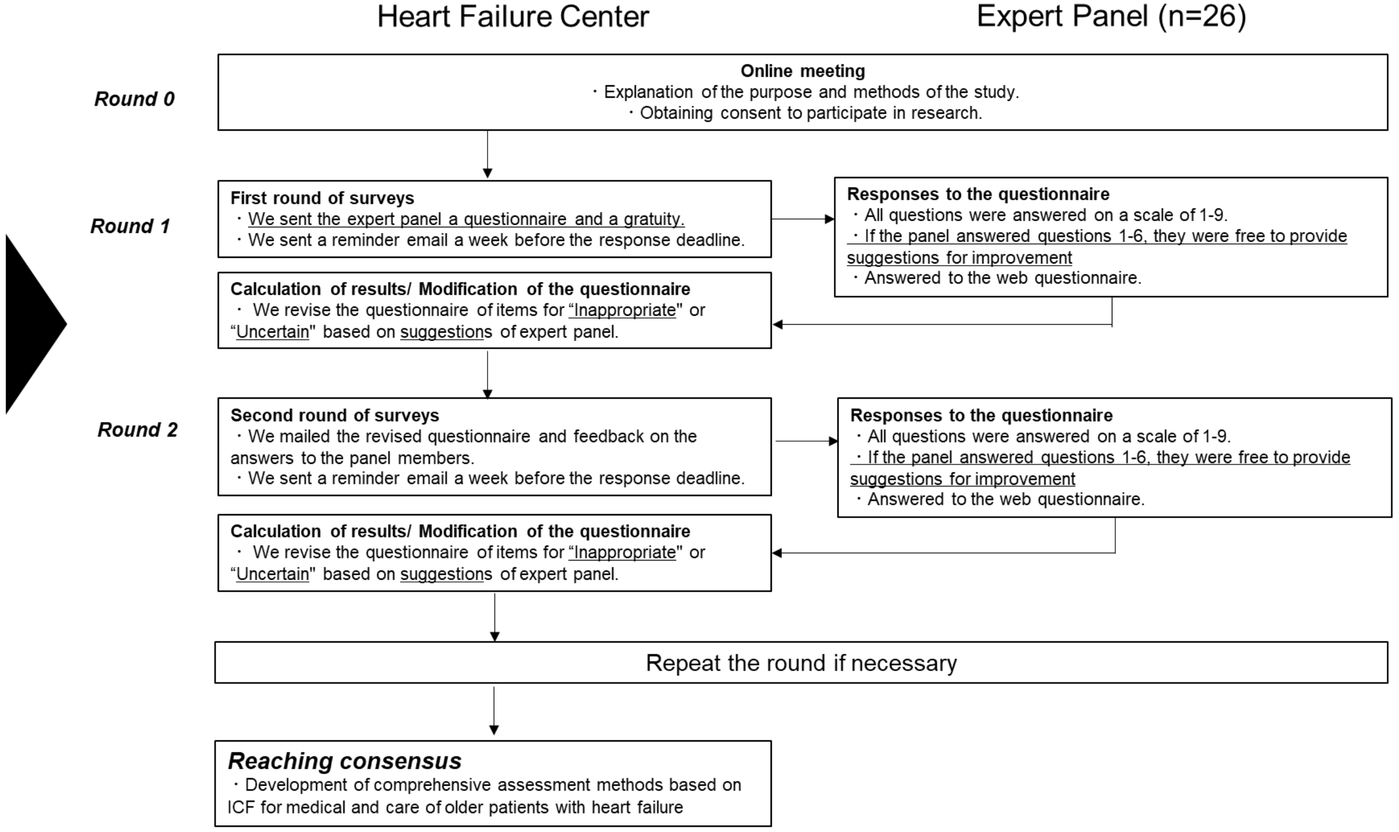
Development of the questionnaire

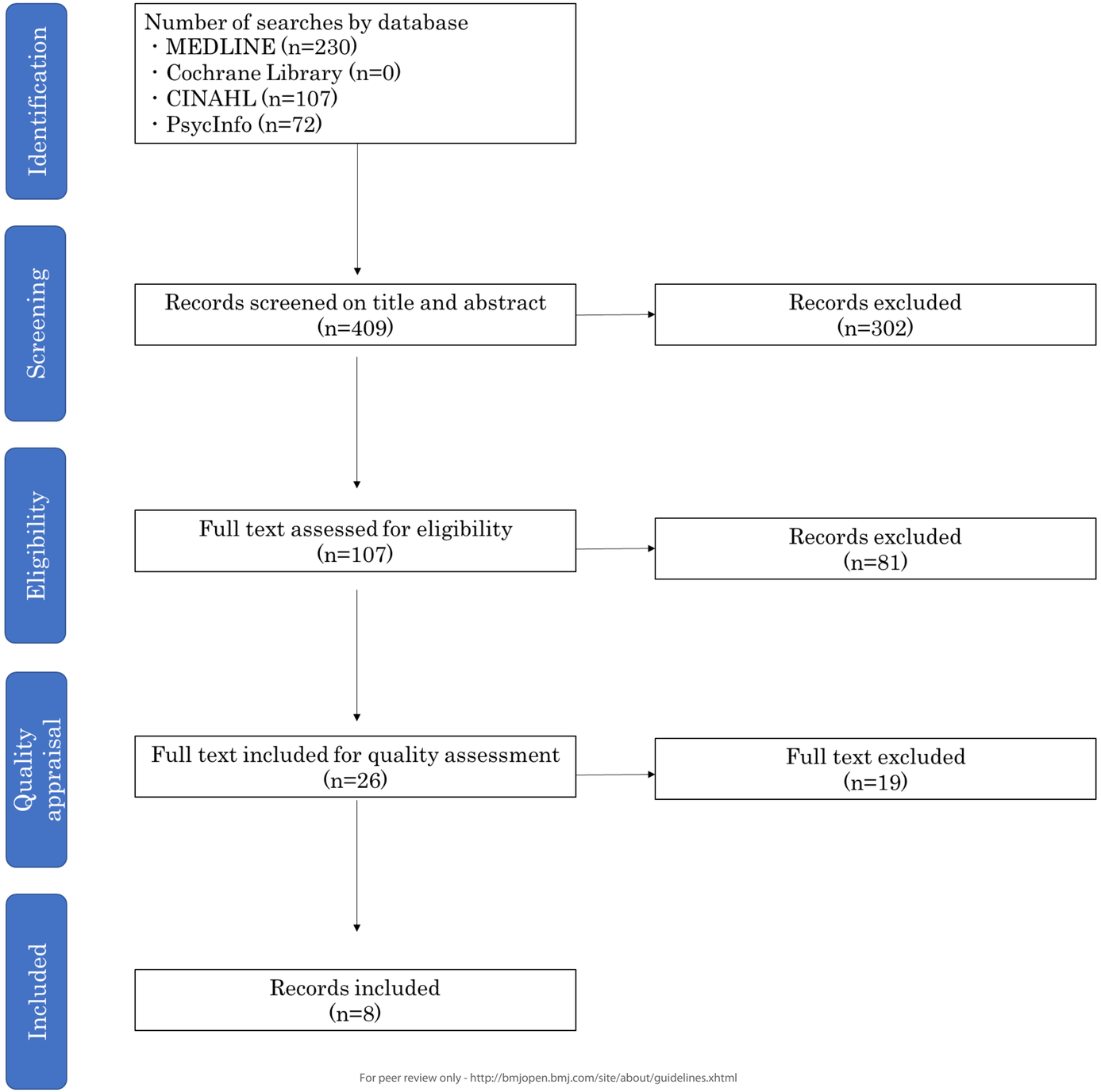
Selection of ICF categories for comprehensive assessment in medical and care of older patients with heart failure: Our previous research
・The Delphi survey among registered instructors of cardiac rehabilitation [34]
・The survey of necessary for care planning for care managers in Japan [35]
・We selected 43 ICF categories for a comprehensive assessment of older people with heart failure.

Literature review: ICF linking rules
We conducted a scoping review of ICF linking rules for the comprehensive assessment of older people with heart failure (43 ICF categories).

Development of the questionnaire:
Appropriateness of the description and scoring methods of the ICF-based assessment for older people with heart failure
Questionnaire items: Responses were obtained on a 1-9 Likert scale. (1: very inappropriate – 9: very appropriate)
1) Appropriateness of ICF 43 category scoring descriptions.
2) Appropriateness of existing assessment batteries linked to each ICF categories.
3) Appropriateness of the scoring methods for each ICF categories linked to existing assessment batteries.

Delphi approach




Identification
Screening
Eligibility
Quality appraisal
Included
Number of searches by database
・MEDLINE (n=230)
・Cochrane Library (n=0)
・CINAHL (n=107)
・PsycInfo (n=72)
Records screened on title and abstract (n=409)
Records excluded (n=302)
Full text assessed for eligibility (n=107)
Records excluded (n=81)
Full text included for quality assessment (n=26)
Full text excluded (n=19)
Records included (n=8)

Supplemental materials 1

Questionnaire

"For each ICF category, please indicate on a scale of 1 (very inappropriate) to 9 (very appropriate) the appropriateness of the following three questions.

(1-3: not appropriate, 4-6: undecided, 7-9: appropriate)"

Questionnaire items

1) Appropriateness of ICF 43 category scoring descriptions.

2) Appropriateness of existing assessment batteries linked to each ICF categories.

3) Appropriateness of the scoring methods for each ICF categories linked to existing assessment.

b110: Consciousness function

General mental functions of the state of awareness and alertness, including the clarity and continuity of the wakeful state.

Inclusions: functions of the state, continuity, and quality of consciousness; loss of consciousness; coma, vegetative states, fugues, trance states, possession states, drug-induced altered consciousness, delirium, stupor

*Exclusions: orientation functions (**b114**); energy and drive functions (**b130**); sleep functions (**b134**)*

1) Appropriateness of b110: consciousness function scoring descriptions.

Ratings

0 No problem

1 Mild problem: May include problems with consciousness functions that do not affect the patient's daily activities.

2 Moderate problem: May include a problem with consciousness functions that exceeds 1, but remains a relatively minor problem (<50%).

3 Severe problem: May include a major problem (≧50%) in consciousness functions.

4 Complete problem: May include a complete problem with consciousness functions, such as coma.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

2) Appropriateness of existing assessment batteries linked to b110: consciousness function

Existing assessment battery linked to b110 consciousness function: Japan Coma Scale

Japan Coma Scale

JCS0 (alert)

JCS Ⅰ (not fully alert but awake without any stimuli)

1: Almost clear consciousness, but not clear.

2: Disorientation (not knowing places, times or dates)

3: Cannot say his/her name or date of birth

JCS Ⅱ (arousable with stimulation)

10: Easy eye-opening with a normal call.

20: Eyes open with loud voice or body shaking

30: Eyes open by repeated calls with pain stimulus.

JCSⅢ(unarousable)

100: Movement to repel the pain stimulus.

200: Slight limb movement or frowning in response to the pain stimulus

300: Does not respond to pain stimulus

[Reference]

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Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

3) Appropriateness of the scoring methods for b110 consciousness function linked to Japan Coma Scale.

Ratings

0 No problem: JCS 0

1 Mild problem: JCSⅠ-1 ～ JCSⅠ-3

2 Moderate problem: JCSⅡ-10 ～ JCSⅡ-30

3 Severe problem: JCSⅢ-100 ～ JCSⅢ-200

4 Complete problem: JCSⅢ-300

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

b114: Orientation functions

General mental functions of knowing and ascertaining one's relation to time, to place, to self, to others, to objects, and to space.

Inclusions: functions of orientation to time, place and person; orientation to self and others; disorientation to time, place, and person

Exclusions: consciousness functions (b110); attention functions (b140); memory functions (b144)

1) Appropriateness of b114: Orientation functions scoring descriptions.

Ratings

0 No problem

1 Mild problem: May include problems with orientation functions that do not affect the patient's daily activities.

2 Moderate problem: May include a problem with orientation functions that exceeds 1, but remains a relatively minor problem (<50%).

3 Severe problem: May include a major problem (≧50%) in orientation functions.

4 Complete problem: May include a complete problem with orientation functions.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

2) Appropriateness of existing assessment batteries linked to b114: Orientation functions

Existing assessment battery linked to b114: Orientation functions: Mini-Mental State Examination

Mini-Mental State Examination

Orientation: time

Year, Month, Day, Date, Time: ___/5

Orientation: place

Country, Town, District, Hospital, Ward: ___/5

[Reference]

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Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

3) Appropriateness of the scoring methods for b114: Orientation functions linked to Mini-Mental State Examination

Ratings

0 No problem: MMSE; orientation score 5 (Adopt low scores of time or place)

1 Mild problem: MMSE; orientation score 4 (Adopt low scores of time or place)

2 Moderate problem: MMSE; orientation score 3 (Adopt low scores of time or place)

3 Severe problem: MMSE; orientation score 2 (Adopt low scores of time or place)

4 Complete problem: MMSE; orientation score 1-0 (Adopt low scores of time or place)

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

[Reference]

Vriendt PD, Gorus E, Bautmans I, et al. Conversion of the Mini-Mental State Examination to the International Classification of Functioning, Disability and Health terminology and scoring system. Gerontology. 2012;58(2):112-9. doi: 10.1159/000330088.

b130 Energy and drive functions (Mental functions that cause self-driven activities in daily life.**)**

General mental functions of physiological and psychological mechanisms that cause the individual to move towards satisfy specific needs and general goals in a persistent manner.

Inclusions: functions of energy level, motivation, appetites, craving (including craving for substances that can be abused), and impulse control

Exclusions: consciousness functions (b110); temperament and personality functions (b126); sleep functions (b134); psychomotor functions (b147); emotional functions (b152)

1) Appropriateness of b130 Energy and drive functions.

Ratings

0 No problem

1 Mild problem: May include problems with energy and drive functions that do not affect the patient's daily activities.

2 Moderate problem: May include a problem with energy and drive functions that exceeds 1, but remains a relatively minor problem (<50%).

3 Severe problem: May include a major problem (≧50%) in energy and drive functions.

4 Complete problem: May include a complete problem with energy and drive functions, such as having no motivation or appetite any time.

Answer: Please tick the number that best applies

Very inappropriate							Very appropriate	
1	2	3	4	5	6	7	8	9

2) Appropriateness of existing assessment batteries linked to b130 Energy and drive functions

Existing assessment battery linked to b130 Energy and drive functions: Vitality Index

Vitality Index

1. Wake up	
Always waking up on time.	2
Sometimes they don't wake up unless you wake them up.	1
They never wake up on their own.	0
2. Communication	
Greet and talk to them yourself.	2
Responding to greetings and calls for help and smiles are observed.	1

No response.	0
3. Feeding	
Willing to eat on their own initiative	2
Attempts to eat when prompted	1
Lack of interest in eating, unwilling to eat at all	0
4. On and Off Toilet	
Always communicate bowel movements and urination on their own, or urinate and defecate on their own	2
Occasional urinary and bowel movements.	1
No interest in excretion at all.	0
5. Rehabilitation, Activity	
Go to rehabilitation on their own and seek out activities.	2
Participate in rehabilitation and activities when prompted	1
Rejection, indifference.	0
Total	/10

[Reference]

1. Kenji Toba, Ryuhei Nakai, Masahiro Akishita et al: Vitality Index as a useful tool to assess elderly with dementia. Geriatr Gerontol Int 2002; 2: 23-9.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

3) Appropriateness of the scoring methods for b130 Energy and drive functions linked to Vitality Index

Ratings

0 No problem: Vitality Index; Total 10

1 Mild problem: Vitality Index; Total 9-7

2 Moderate problem: Vitality Index; Total 6-4

3 Severe problem: Vitality Index; Total 3-1

4 Complete problem: Vitality Index; Total 0

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

b134 Sleep functions (Extent and frequency of the problem, such as shortage of sleep or irregular sleep schedules**)**

General mental functions of periodic, reversible and selective physical and mental disengagement from one's immediate environment accompanied by characteristic physiological changes.

Exclusions: Attention functions (b140), Consciousness functions (b110), Energy and drive functions (b130), Psychomotor functions (b147)

1) Appropriateness of b134 Sleep functions.

Ratings

0 No problem

1 Mild problem: May include problems with sleep that do not affect the patient's daily activities.

2 Moderate problem: May include a problem with sleep that exceeds 1, but remains a relatively minor problem (<50%).

3 Severe problem: May include a major problem (≧50%) in sleep.

4 Complete problem: May include a complete problem with sleep, such as being incapable of sleeping, or a complete day–night reversal every day.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

2) Appropriateness of existing assessment batteries linked to b134 Sleep functions.

Existing assessment battery linked to b134 Sleep functions: Pittsburgh Sleep Quality Index

Prepared with reference to the Pittsburgh Sleep Quality Index.

1. Amount of sleep: During the past month, how hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed)	
Over 7 hours	0
6-7 hours	1
5-6 hours	2
Less than 5 hours	3
2. Onset of sleep: During the past month, how often have you had trouble sleeping because you cannot get to sleep within 30 minutes	

Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3
3. Maintenance of sleep: During the past month, how often have you had trouble sleeping because you wake up in the middle of the night or early morning	
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3
4. Quality of sleep: During the past month, how would you rate your sleep quality overall?	
Very good	0
Fairly good	1
Fairly bad	2
Very bad	3

[Reference]

1. Buysse DJ, Reynolds CF, Charles F, et al (1989). The Pittsburgh sleep quality index: a new instrument for psychiatric practice and research. Psychiatry Research, 28 (2), 193–213.

2. Doi Y, Minowa M, Uchiyama M, et al. Psychometric assessment of subjective sleep quality using the Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J) in psychiatric disordered and control subjects. Psychiatry Res. 2000 Dec 27;97(2-3):165-72. doi: 10.1016/s0165-1781(00)00232-8.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

3) Appropriateness of the scoring methods for b134 Sleep functions linked to Pittsburgh Sleep Quality Index

Ratings

0 No problem: All items scored 0.

1 Mild problem: Lowest item scores 1

2 Moderate problem: Lowest item scores 2

3 Severe problem: Lowest item scores 3

4 Complete problem: Lowest item scores 1 and use of sleeping pills does not improve the problem

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

b164 Higher-level cognitive functions

Specific mental functions especially dependent on the frontal lobes of the brain, including complex goal-directed behaviours such as decision-making, abstract thinking, planning and carrying out plans, mental flexibility, and deciding which behaviours are appropriate under what circumstances; often called executive functions.

Inclusions: categorization, concept formation, cognitive flexibility

Exclusions: Calculation functions (b172), Memory functions (b144), Mental functions of language (b167), Thought functions (b160)

1) Appropriateness of b164 Higher-level cognitive functions.

Ratings

0 No problem

1 Mild problem: May include problems with **higher-level cognitive functions** that do not affect the patient's daily activities.

2 Moderate problem: May include a problem with **higher-level cognitive functions** that exceeds 1, but remains a relatively minor problem (<50%).

3 Severe problem: May include a major problem (≧50%) in **higher-level cognitive functions**.

4 Complete problem: May include a complete problem with **higher-level cognitive functions.**

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

2) Appropriateness of existing assessment batteries linked to b164 Higher-level cognitive functions.

Existing assessment battery linked to b164 Higher-level cognitive functions: Frontal Assessment Battery

Frontal Assessment Battery

[Reference]

1. Dubois B, Slachevsky A, Litvan I, et al. The FAB: a Frontal Assessment Battery at bedside. Neurology. 2000 Dec 12;55(11):1621-6. doi: 10.1212/wnl.55.11.1621.

2. Nakaaki S, Murata Y, Sato J, et al. Reliability and validity of the Japanese version of the

Frontal Assessment Battery in patients with the frontal variant of frontotemporal dementia. Psychiatry Clin Neurosci. 2007 Feb;61(1):78-83. doi: 10.1111/j.1440-1819.2007.01614.x.

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

3) Appropriateness of the scoring methods for b164 Higher-level cognitive functions linked to Frontal Assessment Battery

Ratings

0 No problem: FAB Total scores18-16

1 Mild problem: FAB Total scores15-14

2 Moderate problem: FAB Total scores13-9

3 Severe problem: FAB Total scores8-5

4 Complete problem: FAB Total scores4-0

Answer: Please tick the number that best applies

Very inappropriate								Very appropriate
1	2	3	4	5	6	7	8	9

This is followed by questions on b410: Heart function, b415: Blood vessel function and others and a total of 43 ICF categories.

Supplemental material 2

Results of the literature review of the ICF linking Rules: correspondence table of 43 ICF categories and linked existing assessment batteries.

Study	Darzins SW, et al (2017) [46]	Milman N, et al (2015) [42]	Hoang-Kim A, et al (2013). [43]		Cieza A, et al (2005). [44]					Prodinger B, et al (2019) [47]		Alarcos Cieza (2008) [45]	Bladh S, et al (2013) [41]				Prodinger B, et al (2017) [40]	
Assessment batteries	**FIM**	**SF-36**	**EQ-5D**	**SF-36**	**EQ-5D**	**SF-36**	**NHP**	**WHODAS 2.0**	**WHOQOL-CHEF**	**WHODAS 2.0**	**SF-36**	**SF-36**	**FES-I**	**FES(S)**	**ABC**	**SAFFE**	**FIM**	**Birthel Index**
b110																		
b114																		
b130		✔		✔			✔		✔			✔						
b134							✔		✔									
b164																		
b410																		
b415																		
b420																		
b440																		
b455																		
b460																		
b525	✔																	
b530																		
b540																		
b620	✔																	
b710																		
b730																		
s410																		

d177																		
d230				✔	✔	✔		✔	✔									
d310								✔										
d330																		
d420				✔						✔								
d450	✔		✔	✔	✔	✔	✔						✔		✔	✔	✔	✔
d510	✔		✔	✔	✔	✔		✔		✔			✔	✔		✔		✔
d520	✔									✔								
d530	✔									✔				✔			✔	✔
d540	✔		✔	✔	✔	✔	✔	✔					✔	✔			✔	✔
d550	✔							✔										✔
d560	✔																	
d570																✔		
d620										✔			✔	✔		✔		
d630							✔			✔			✔			✔		
d640			✔	✔				✔					✔	✔	✔	✔		
d710																		
d760			✔	✔	✔													
d920			✔	✔	✔	✔	✔	✔	✔				✔			✔		
e310																		
e340																		
e355																		
e410																		
e575																		
e580									✔									

Functional Independence Measure (FIM), Short-Form 36 health survey (SF-36), EuroQol 5 dimensions (EQ-5D), the Nottingham Health Profile(NHP), the World Health Organization Disability Assessment Schedule (WHODAS 2.0), the World Health Organization Quality of Life Assessment (WHOQOL-BREF)

Falls Efficacy Scale-International (FES-I), the Swedish version of the Falls Efficacy Scale (FES[S]), the Activities-specific Balance Confidence Scale (ABC), the modified Survey of Activities and Fear of Falling in the Elderly (SAFFE)

Supplemental material 3

Results of the three questions of the 43 ICF categories in the first Delphi round

ICF categories		Existing assessment batteries linked to ICF categories	Question Items					
			1) Appropriateness of ICF 43 category scoring descriptions		2) Appropriateness of existing assessment batteries linked to each ICF categories		3) Appropriateness of the scoring methods for each ICF categories linked to existing assessment batteries	
			median score (/9)	Number of outside median tertile (/21)	median score (/9)	Number of outside median tertile (/21)	median score (/9)	Number of outside median tertile (/21)
b110	Consciousness function	Japan Coma Scale	7	7	8	1	7	4
b114	Orientation function	Mimi-Mental State Examination	8	6	8	2	8	4
b130	Energy and drive function	Vitality Index	7	7	8	2	8	2
b134	Sleep function	-	**7**	**9**	-	-	-	-
b164	Higher-level cognitive functions	Frontal Assessment Battery	7	6	7	7	7.5	4
b410	Heart function	Echocardiography; left ventricular function, Electrocardiogram	7	4	**7**	**8**	**7**	**11**
b415	Blood vessel function	Fontaine classification	7	5	8	2	8	4
b420	Blood pressure function	Blood pressure	7	6	7.5	4	8	4
b440	Respiration function	Arterial Blood Gas Analysis, fraction of inspiratory oxygen, SpO_2, Respiration Rate	8	4	8	4	7	5
b455	Exercise tolerance function	Specific Activity Scale	8	3	7.5	1	7	3
b460	Sensations associated with cardiovascular and respiratory functions	NYHA classification	8	4	8	3	8	2
b525	Defaecation function	-	7	6	7	4	-	-
b530	Weight maintenance functions	Body Mass Index	7	6	8	3	8	4
b545	Water, mineral and electrolyte balance functions	Blood test: Na, K	7.5	5	8	4	7.5	6

b620	Urination function	-	7	5	8	2	-	-
b710	Mobility of joint function	Range Of Motion	8	4	7	4	7	5
b730	Muscle power function	Manual Muscle Test or five-times sit-to-stand	8	4	7.5	5	7.5	6
s410	Structure of the cardiovascular system	Echocardiography; Severity of valve function Chest radiograph; CTR	7	5	**7**	**9**	**7**	**9**
d177	Making decisions	-	8	3	-	-	-	-
d230	Carrying out daily routine	-	8	2	-	-	-	-
d310	Communicating with-receiving-spoken messages	FIM; Comprehension	7.5	5	8	4	8	4
d330	Speaking	FIM; Expression	8	5	**7**	**8**	7	7
d420	Transferring oneself	FIM; Transfers	8	3	8	0	8	2
d450	Walking	FIM; Walk 5-m walk test	8	4	7	5	7	5
d510	Washing oneself	FIM; Bathing	8	3	8	4	7	4
d520	Caring for body parts	FIM; Grooming	8	4	7.5	2	7	4
d530	Toileting	FIM; Toileting	7	4	8	1	8	4
d540	Dressing	FIM; Dressing	8	4	7.5	2	7	4
d550/ d560	Eating/ Drinking	FIM; Eating	8	4	8	3	8	5
d570	Looking after one's health	-	7.5	3	-	-	-	-
d620	Acquisition of goods and services	Instrumental Activities of Daily Living scale; Shopping	7.5	4	8	4	7	5
d630	Preparing meals	Instrumental Activities of Daily Living scale; Food preparation	7	7	7.5	3	7	6
d640	Doing housework	Instrumental Activities of Daily Living scale; Housekeeping	7	5	7	2	7	4
d710	Basic interpersonal interactions	-	8	2	-	-	-	-
d760	Family relationships	-	8	3	-	-	-	-
d920	Recreation and leisure	-	8	4	-	-	-	-
e310	Immediate family	-	8	4	-	-	-	-
e340	Personal care providers and personal assistants	-	7	4	-	-	-	-
e355	Health professionals	-	8	4	-	-	-	-

e410	Individual attitudes of immediate family members	-	7.5	5	-	-	-	-
e575	General social support services, systems, and policies	-	7.5	5	-	-	-	-
e580	Health services, systems, and policies	-	7.5	3	-	-	-	-

SpO2, oxygen saturation; NYHA, New York Heart Association; CTR, cardiothoracic ratio; FIM, Functional Independence Measure.

Bolded text indicates items of disagreement.