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

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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

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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

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

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

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6 [25,26] The 43 ICF categories specific to older patients with heart failure consisted of 17
7 body functions and one body structure, 19 activities and participation in the same, and 6
8 environmental factors. However, in order to utilise a comprehensive assessment based
9 on the ICF in clinical practice, it is necessary to develop guidelines for the assessment
10 of the 43 ICF categories and to verify their appropriateness.
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13 The purpose of this study was to develop a scoring method of older patients with heart
14 failure based on the ICF, and to determine its appropriateness using the Delphi technique.
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17 **METHOD**

18 **Patient and public involvement**

19 Patients and the public are not involved in the design, planning, conduct or reporting of
20 this study.
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24 **Design**

25 We applied the Delphi method to an expert panel. The Delphi method is a consensus
26 method used in the development of guidelines and clinical indicators, and is effective in
27 guiding assessments and treatments for which there is limited evidence. The Delphi
28 method is also a standard practice in the development of ICF Core Sets. [27] We
29 developed a questionnaire based on the literature review and structured a two-stage
30 survey with an expert panel, referring to the RAND/UCLA appropriateness methodology.
31 [28] (Figure 1).
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38 **Establishing of the expert panel**

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

54 We developed scoring guidelines and linking of the assessment batteries to the 43 ICF
55 categories selected from previous studies by medical professionals and care
56 professionals. [25,26] To develop the questionnaire, we first conducted a literature
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6 review of the ICF linking rules. The ICF linking rules are a systematic methodology for
7 linking the existing assessment batteries to the ICF codes. [30,31] All articles related to
8 the ICF linking rule from January 2005 to August 2020 were included in the study. We
9 used MEDLINE (PubMed), Cochrane Library, CINAHL, and PsycInfo as electronic
10 article databases. The search terms in the electronic article database were "ICF" and
11 "Linking rule" or "Rasch" in medical subject headings (MeSH). The search criteria were
12 as follows: (1) written in English, (2) cross-sectional study, cohort study, or case-control
13 study, (3) target group of people aged 18 years or older, (4) use of an existing evaluation
14 battery, (5) results from ICF data or Rasch analysis of the ICF data, and (6) "ICF" and
15 "linking rule" present in the title. The literature review was carried out by five authors (SS,
16 NG, HF, SN, and YT) in two phases. In the first phase, the appropriateness of the titles
17 and abstracts were assessed based on the search criteria. In the second phase, the full
18 text was assessed. Finally, we carried out a qualitative analysis of articles to identify links
19 to assessment batteries and scoring systems associated with the 43 ICF categories. We
20 completed the questionnaire based on the results of this literature review and the
21 explanatory notes in the ICF Reference Guide. [32,33] The Delphi questionnaire
22 consisted of the following three questions regarding the appropriateness of the 43 ICF
23 categories as follow; (i) the grade guidelines, (ii) the evaluation battery linked to the ICF
24 categories, and (iii) the scoring guidelines for the evaluation battery linked to the ICF
25 categories. All questionnaires were developed using a Google Form, with a description
26 of each ICF category and the rationale for scoring.
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39 **Delphi process and funding consensus**

40 The Delphi process for reaching a consensus is shown in Figure 1. Before conducting
41 the Delphi survey, the Heart Failure Center (HFC) held an online meeting for the panel
42 members. In the online meeting, we explained the purpose of our study and the methods
43 of the Delphi process to the panel members and obtained their consent to participate in
44 the study. In the Delphi study, the panel members assessed the appropriateness of the
45 following questionnaire items: (1) guidelines for scoring the 43 ICF categories for elderly
46 patients with heart failure, (2) a rating battery linked to the ICF categories, and (3)
47 guidelines for scoring the linked rating battery. To assess the appropriateness, we used
48 a nine-point Likert scale ranging from 1 (very inappropriate) to 9 (very appropriate). Panel
49 members were also asked to freely describe the items that they thought needed revision.
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52 In the first round, the HFC mailed a sheet with instructions on how to conduct the ICF
53 category adequacy assessment, as well as the URL and QR codes for the questionnaire.
54 The panel members rated the "appropriateness" of the questions in each ICF category
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6 on a scale of 1 to 9. The HFC had the panel members tabulate their responses and they
7 modified the questionnaire based on the panel's comments. In the second round, the
8 HFC emailed the revised questionnaire and feedback based on the panel members'
9 responses. As in the first round, the panel members rated the appropriateness of all the
10 ICF category questions and wrote freely about items that they thought needed to be
11 modified. The HFC compiled the panel members' responses and assessed their
12 appropriateness. We also modified the questionnaire based on the panel's comments.
13 The revised questionnaire was emailed to the panel members, and a final consensus
14 was reached after confirming that there were no comments for revision.
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20 **Analysis**

21 Guided by the RAND/UCLA appropriateness methodology.[28], we used the median
22 of the responses from the panellists to assess appropriateness. Appropriateness was
23 evaluated on the following three levels: "Appropriate", a median panel value of 7-9 with
24 no disagreement; "Uncertain", a median panel value of 4-6, or any median value with
25 which there is no disagreement; "Inappropriate", a median panel value of 1-3, with no
26 disagreement. The definition of agreement consent is defined as follows: "Agreement",
27 80% or more of the respondents' medians are within the same region (1-3, 4-6, 7-9) as
28 the median.
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36 **Ethics**

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

51 **Characteristics of the expert panel participants**

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

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36 and Euro QoL-5D.

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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).

25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 **Delphi round 1**

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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.

41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 **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 (%)
Consciousness function	Japan Coma Scale	8	85.7	9	90.5	9	95.2
Orientation function	Mimi-Mental State Examination	8	85.7	8	81.0	9	90.5
Energy and drive function	Vitality Index	8	90.5	8, 9	85.7	8, 9	90.5
Sleep function	Pittsburgh Sleep Quality Index	8	90.5	9	90.5	9	81.0
Higher-level cognitive functions	Frontal Assessment Battery	7	90.5	8	90.5	9	85.7
Heart function	Echocardiography; left ventricular function, Electrocardiogram	7, 8	81.0	9	85.7	8, 9	85.7
Blood vessel function	Fontaine classification	7, 8	81.0	7, 9	90.5	9	81.0
Blood pressure function	Blood pressure	7, 8	81.0	9	95.2	9	90.5
Respiration function	SpO ₂ , Respiration Rate	8	90.5	8	85.7	8	95.2
Exercise tolerance function	Specific Activity Scale	9	90.2	9	85.7	9	95.2
Sensations associated with cardiovascular and respiratory functions	NYHA classification	9	90.5	9	95.2	9	95.2
Defaecation function	-	8	85.7	-	-	-	-
Weight maintenance functions	Body Mass Index	8	85.7	9	85.7	9	85.7
Water, mineral and electrolyte balance functions	Blood test: Na, K	7, 9	81.0	7, 9	85.7	7	85.7
Urination function	-	8	81.0	-	-	-	-
Mobility of joint function	Range Of Motion	8	85.7	8	85.7	7, 8	90.5
Muscle power function	Manual Muscle Test or five-times sit-to-stand	8	85.7	7	85.7	8	81.0
Structure of the cardiovascular system	Echocardiography; Severity of valve function	7	85.7	7	85.7	7	90.5

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		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	-	-	-	-
d310	Immediate family	-	8	85.7	-	-	-	-
d340	Personal care providers and personal assistants	-	9	90.5	-	-	-	-
d355	Health professionals	-	8	95.2	-	-	-	-
d410	Individual attitudes of immediate family members	-	8	90.5	-	-	-	-
d575	General social support services, systems, and policies	-	8	90.5	-	-	-	-
d580	Health services, systems, and policies	-	7	85.7	-	-	-	-

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7 SpO₂, oxygen saturation; NYHA, New York Heart Association; CTR, cardiothoracic ratio;
8 FIM, Functional Independence Measure.
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10 11 12 13 **DISCUSSION**

14 We have developed a comprehensive assessment of older people with heart failure for
15 widespread use in clinical practice and validated the scoring method using the RAND
16 Delphi method. The results of the two-round Delphi process were judged to be
17 "appropriate" in all 43 ICF categories of questions and "agreement" in all 43 ICF
18 categories, except for the scoring guidelines for supplementary criteria for d450 walking.
19 In the d450 walking, we had to reach a consensus through the modifications based on
20 the panel members' comments.
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25 The purpose of this study was to develop an assessment method that could be used
26 not only by cardiologists but also by medical professionals: general practitioners, care
27 managers and paramedical professions. Therefore, we adopted a simple evaluation
28 method that requires as little special machinery and environment as possible. For
29 example, although exercise tolerance at b455 has been reported to be a prognostic
30 factor for heart failure.[43], we avoided cardiopulmonary exercise testing (CPX). [44-46]
31 and the 6-minute walk test. [47] and chose specific activity scale (SAS) instead. [48] In
32 the d450 walking, we used two assessment batteries, gait speed and FIM, as
33 supplementary criteria, but the agreement rate did not exceed 80% in the second Delphi
34 study. Although gait speed is a prognostic factor for heart failure patients over 65 years
35 of age.[16], we adopted FIM only as an auxiliary criterion for simplicity of assessment,
36 and obtained a consensus from the panel members. However, the 43 items in the current
37 ICF did not include renal function, BNP, and anaemia, which are prognostic factors for
38 heart failure. [49] We suggest that these items be added, although the increase in the
39 items may prevent their wide-spread use in the clinical setting, making their clinical use
40 more difficult. In addition, the 43 ICF categories assessment instrument developed in this
41 study did not include personal factors such as age, sex, values, lifestyle, coping, and
42 personality. In the care of chronic diseases, patient-centred intervention is the
43 principle.[50], and patient-centred care is also recommended in the ESC guidelines. [51]
44 We propose that personal factors need to be included when developing an ICF
45 information-sharing system.
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56 In Japan, the establishment of a comprehensive community care system that integrates
57 medical care, welfare, and nursing care is being promoted, but evidence for information
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6 sharing is lacking. We expect that the ICF-based assessment method for older patients
7 with heart failure developed in this study will be widely used in clinical practice.
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10 **Strengths and limitations**

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

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

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

Provenance and peer review

Not commissioned; externally peer reviewed.

Data availability statement

Data are available upon reasonable request.

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6 **Figure Legends**
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8 Fig. 1: Development of Questionnaire and Delphi process flow
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13 Fig. 2: Selection of records and process flow diagrams
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For peer review only

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 battery linked to each ICF categories
 3) The appropriateness of the scoring guidelines for the evaluation battery linked to each ICF categories

Delphi approach

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.

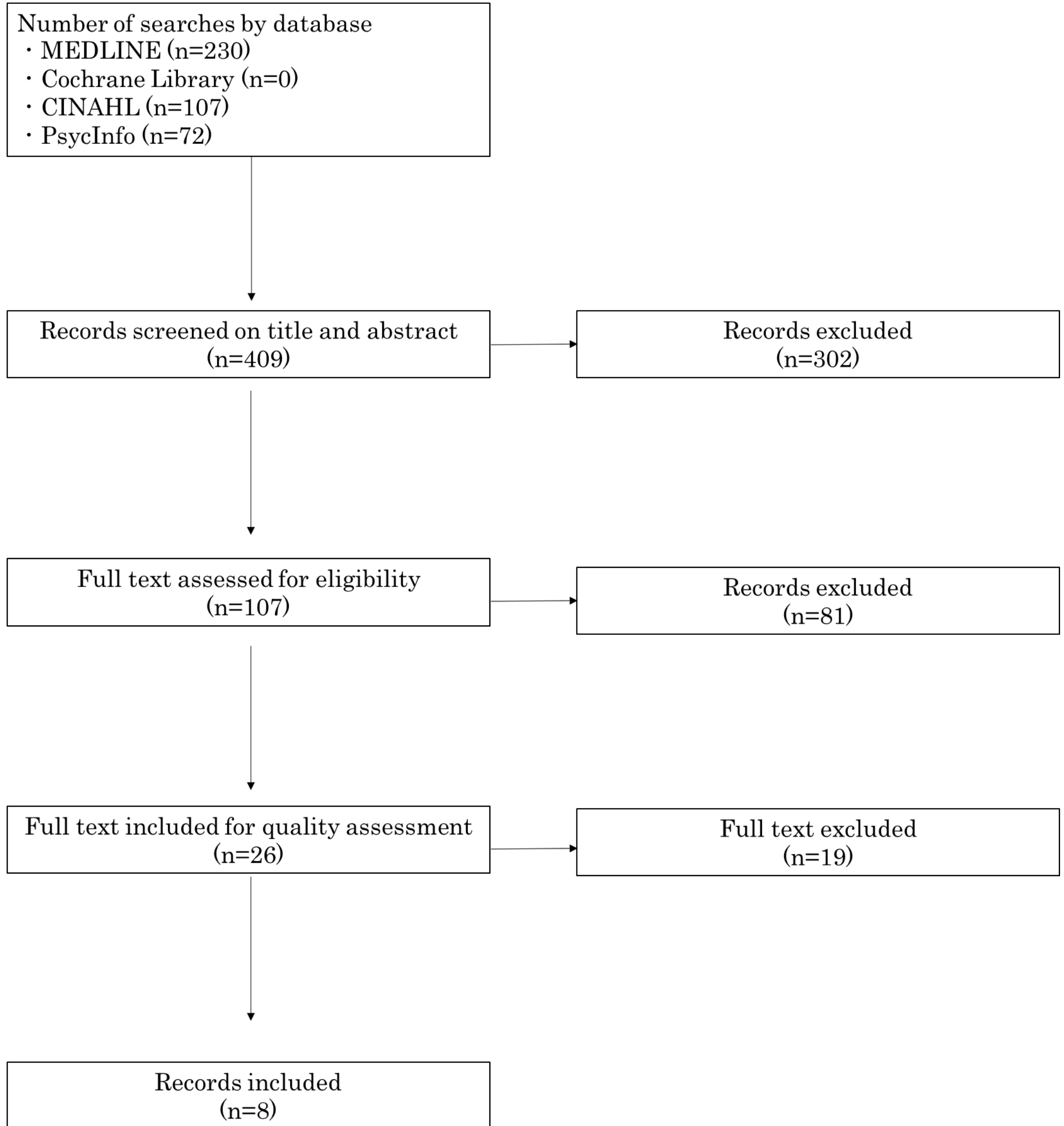
Repeat the round if necessary

Reaching consensus
 · Development of comprehensive assessment methods based on ICF for medical and care of older patients with heart failure



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Identification
Screening
Eligibility
Quality appraisal
Included



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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-060609.R1
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1 Original research

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

6

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34 **ABSTRACT**

35 **Objective:** The number of older patients with heart failure (HF) is increasing in Japan
36 and has become a social problem. There is an urgent need to develop a comprehensive
37 assessment methodology based on the common language of health care; the
38 International Classification of Functioning, Disability and Health (ICF). The purpose of
39 this study was to develop and confirm the appropriateness of a scoring methodology for
40 43 ICF categories in older people with HF.

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

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

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

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

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

61
62 **Keywords:** heart failure, older people, ICF, scoring methods, RAND/UCLA
63 Appropriateness Method

64 65 **Strengths and limitations of this study**

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

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6 70 ▶ The assessment domains studied the 43-item ICF relevant to older adults with heart
7 71 failure, covering not only the medical assessment but also the physical and mental
8 72 functioning, activity and social participation, and environmental factors.
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10 73 ▶The expert panel comprised general practitioners, cardiologists, and paramedical
11 74 professions (rehabilitation, nursing care, and welfare), but caution is needed in
12 75 generalizing the findings because of the study's limited geographical area.
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77 INTRODUCTION

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

86 Among cardiovascular diseases, heart failure (HF) is increasing with the ageing of the
87 population, with the number of patients in Japan expected to exceed 1.3 million by 2030.
88 [6,7] HF reduces the quality of life of patients and their families by repeated
89 rehospitalizations due to exacerbations, and the increased burden of medical expenses.
90 [8-10] The one-year readmission rate for patients with HF is 35% in Japan, but a study
91 of elderly patients with HF in the United States reported a rate of 64%. [11,12] Elderly
92 patients with HF have multiple comorbidities, such as atrial fibrillation, chronic renal
93 failure, dementia, and depression, which are factors associated with readmission. [13] In
94 addition, many factors have been reported to be associated with readmission in patients
95 with HF, including cognitive function, depression/anxiety, exercise tolerance, muscle
96 strength, walking speed, activities of daily living (ADL), and instrumental activities of daily
97 living (IADL). [14-18] The Guideline on Diagnosis and Treatment of Acute and Chronic
98 Heart Failure (JCS 2017/ JHFS 2017) recommends that patients with limited self-care
99 capabilities, such as elderly patients with HF, should receive education and support from
100 their families and actively utilise social resources such as home physicians and home-
101 visit nursing. [19] Social support and information sharing in the community have been
102 reported to prevent HF readmissions, and there is an urgent need to establish an
103 information sharing system between medical professionals and care professionals in the
104 community. [20,21]

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

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6 113 World Health Organisation provides the ICF Core Set and the ICF Linking Rules. The
7 114 ICF Core Set is a set of identified ICF categories for assessing a patient's special health
8 115 condition or special medical background. [29] The ICF Linking Rules are a method of
9 116 linking ICF categories with existing assessment methods. [30,31] The ICF core set for
10 117 chronic ischaemic heart disease and the Geriatric ICF core set have already been
11 118 developed, but these ICF categories are not appropriate for adaptation to older patients
12 119 with heart failure. [32,33] Therefore, 43 ICF categories were selected for the
13 120 comprehensive assessment of older patients with HF through the questionnaire survey
14 121 of a multidisciplinary group of medical professionals and care professionals. [34,35] The
15 122 43 ICF categories specific to older patients with HF consisted of 17 body functions and
16 123 one body structure, 19 activities and participation, and 6 environmental factors. However,
17 124 in order to efficiently utilize ICF-based assessments in clinical practice, it is necessary to
18 125 develop scoring methods linked to existing assessments.

19 126 The purpose of this study was to develop a scoring method of older patients with HF
20 127 based on the ICF, and to determine its appropriateness using the Delphi technique.
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23 130 **METHOD**

24 131 **Patient and public involvement**

25 132 Patients and the public are not involved in the design, planning, conduct or reporting of
26 133 this study.
27 134

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29 136 **Design**

30 137 We applied the Delphi method to an expert panel. The Delphi method is a consensus
31 138 method used in the development of guidelines and clinical indicators, and is effective in
32 139 guiding assessments and treatments for which there is limited evidence. The Delphi
33 140 method is also a standard practice in the development of ICF Core Sets. [29] We
34 141 developed a questionnaire based on the literature review and structured a two-stage
35 142 Delphi survey with an expert panel, referring to the RAND/UCLA appropriateness
36 143 methodology. [36] (Figure 1).
37 144

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39 146 **Establishing of the expert panel**

40 147 We established an expert multidisciplinary panel consisting of 26 medical and care
41 148 professionals in Hiroshima Prefecture, Japan. The members of the expert committee
42 149 were professionals with leadership roles in community care, all of whom have expertise
43 150 in the assessment, treatment, and care of older patients with heart failure. Five home
44 151 physicians and ten care managers were recommended by the Hiroshima Care Manager
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6 149 Association. All five home physicians are specialists in internal medicine who engage in
7 150 home visits while all ten care managers are board members of the Hiroshima Care
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9 151 Manager Association and leaders in their respective communities. In addition, we
10 152 included 11 medical multidisciplinary professionals involved in HF care at specialised
11 153 medical institutions recommended by the Hiroshima Heart Health Promotion Project in
12 154 our panel .[37] The 11 medical multidisciplinary members were: two cardiovascular
13 155 physicians, three nurses certified in chronic HF nursing, two physiotherapists with
14 156 registered instructors of cardiac rehabilitation, one occupational therapist with registered
15 157 instructors of cardiac rehabilitation, one certified pharmacist, one nutritionist, and one
16 158 social worker.
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160 **Development of the questionnaire**

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

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6 185 existing assessment batteries linked to each ICF categories, and 3) appropriateness of
7 186 the scoring methods for each ICF categories linked to existing assessment batteries. All
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9 187 questionnaires were developed using a Google Form, with a description of each ICF
10 188 category and the rationale for scoring. (Supplemental materials 1).
11
12 189

13 190 **Delphi process and funding consensus**

14
15 191 The Delphi process for reaching a consensus is shown in Figure 1. Before conducting
16 192 the Delphi survey, the HF Centre (HFC) held an online meeting for the panel members.
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18 193 In the online meeting, we explained the purpose of our study and the methods of the
19 194 Delphi process to the panel members and obtained their consent to participate in the
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21 195 study. In the first round, the HFC mailed a sheet with instructions on how to conduct the
22 196 ICF category adequacy assessment, as well as the URL and QR codes for the
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24 197 questionnaire. The panel members responded to three questions in 43 ICF categories
25 198 on a scale of 1-9. In addition, panel members provided open-ended suggestions for
26
27 199 improvements to the questions they scored 1-6. The HFC collated the panel members'
28 200 responses. We revised the scoring descriptions and existing assessment batteries linked
29
30 201 to the ICF categories responded to as 'Inappropriate', 'Uncertain' or 'Disagreement'
31 202 based on the panel's suggestions. The definition of 'Disagreement' in this article is given
32
33 203 in Analysis. In the second round, the HFC emailed the revised questionnaire and
34 204 feedback based on the panel members' responses. As in the first round, the panel
35
36 205 members rated the appropriateness of three question items in the 43 ICF categories. In
37 206 addition, the panel members provided suggestions for improvements to the scoring
38
39 207 methods on those ones scored 1-6. The HFC compiled the panel members' responses
40 208 and assessed their appropriateness. We also revised the descriptions of the
41
42 209 questionnaire or scoring methods based on the panel's suggestions. The revised
43 210 questionnaire was emailed to the panel members, and a final consensus was reached
44
45 211 after confirming that there were no comments for revision.
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48 213 **Analysis**

49 214 Following the RAND/UCLA appropriateness methodology [28], we used the median
50 215 scores of the responses from the panellists to assess appropriateness. We rated the
51 216 appropriateness of the 43 ICF categories for the assessment method as 'Appropriate' if
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53 217 the median respondent's score was 7-9, 'Uncertain' if it was 4-6 and 'Inappropriate' if it
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55 218 was 1-3. In accordance with the RAND/UCLA guidelines, we defined 'Agreement' or
56
57 219 'Disagreement' according to the number of panellists who rated outside the range of
58 220 tertiles (1-3; 4-6; 7-9) including the median. 'Agreement' was defined as fewer than one-

221 third of panellists who rated outside the range of the tertile values. 'Disagreement' was
 222 defined as when more than one-third of panellists rated the extremes (1-3 range and 7-
 223 9 range) not including the median.

224

225 **Ethics**

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

234

235 **RESULTS**

236 **Characteristics of the expert panel participants**

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

241

242 Table 1 Characteristics of the expert panel participants who responded to all Delphi
 243 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)

244

245 **Development of the Delphi questionnaire of ICF assessment method for older** 246 **patients with heart failure**

247 Figure 2 showed the process of literature review. A total of 409 references were
 248 extracted from the literature survey. The breakdown of each article database was as
 249 follows: MEDLINE (PubMed), 230 articles; Cochrane Library, 0 articles; CINAHL, 107
 250 articles; PsycInfo, 72 articles. In the primary screening, 107 references were extracted,
 251 and in the secondary screening, 26 references were extracted. Finally, two references
 252 were excluded, and the total number of eligible references was 26. In the qualitative
 253 analysis, we excluded 19 references dealing with disease-specific assessment batteries
 254 that could not be adapted to older patients with HF (e.g., stroke, musculoskeletal disease,
 255 hand surgery, low back pain). Eight articles on ICF linking rules were included. Finally,
 256 we employed 11 existing assessment batteries on eight articles links to the 43 ICF
 257 categories (Supplemental material 2). [40-47] Eleven existing assessment batteries were
 258 included: assessment of ADL (such as Functional Independence Measure (FIM) and
 259 Barthel Index), assessment of general health-related quality of life (such as Short Form
 260 36 and the European Quality of Life instrument (EQ-5D), The World Health Organization
 261 Quality of Life (WHOQOL)), assessment of general health status (such as the
 262 Nottingham Health Profile(NHP), the World Health Organization Disability Assessment
 263 Schedule (WHODAS 2.0)), and assessment of falls (such as Falls Efficacy Scale-
 264 International (FES-I), the Swedish version of the Falls Efficacy Scale (FES[S]), the
 265 Activities-specific Balance Confidence Scale (ABC), and the modified Survey of Activities
 266 and Fear of Falling in the Elderly (SAFFE)). We identified these existing assessment
 267 batteries as linked to 20 of the 43 categories. However, only the FIM and BI were
 268 employed in the questionnaire, as they did not match the objectives of this study for the
 269 assessment of general health-related quality of life, general health status and falls.
 270 Therefore, we developed a scoring methodology for ICF categories other than ADL,
 271 based on the Italian ICF Guidelines and the ICF Reference Guide. [38,39, 48] Finally,
 272 we decided to provide 30 existing assessment batteries linking to ICF categories, and to
 273 score the remaining 13 categories using only the scoring descriptions (Table 2).

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274

275 Delphi round 1

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

294

295 Delphi round 2

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

309

310

311 Table 2: Results of the three questions of the 43 ICF categories in the second Delphi
312 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)	
10	110	Consciousness function	Japan Coma Scale	8	3	9	2	8	1
11	114	Orientation function	Mimi-Mental State Examination	8	3	8	4	8	2
12	130	Energy and drive function	Vitality Index	8	2	8	3	8	2
13	134	Sleep function	Pittsburgh Sleep Quality Index	8	2	8	2	7	4
14	164	Higher-level cognitive functions	Frontal Assessment Battery	8	2	8	2	8	3
15	410	Heart function	Echocardiography; left ventricular function, Electrocardiogram	7	4	8	3	7	3
16	415	Blood vessel function	Fontaine classification	8	4	8	2	8	4
17	420	Blood pressure function	Blood pressure	8	4	8	1	8	2
18	440	Respiration function	SpO ₂ , Respiration Rate	8	2	8	3	8	1
19	455	Exercise tolerance function	Specific Activity Scale	8	2	8	3	8	1
20	460	Sensations associated with cardiovascular and respiratory functions	NYHA classification	8	2	8	1	9	1
21	525	Defaecation function	-	8	3	-	-	-	-
22	530	Weight maintenance functions	Body Mass Index	8	3	8	3	8	3
23	545	Water, mineral and electrolyte balance functions	Blood test: Na, K	8	4	8	3	7	3
24	620	Urination function	-	8	4	-	-	-	-

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5 6b710	Mobility of joint function	Range Of Motion	8	3	8	3	8	2
7 8b730 9	Muscle power function	Manual Muscle Test or five-times sit-to-stand	8	3	8	3	8	4
10 11 12a10 13 14	Structure of the cardiovascular system	Echocardiography; Severity of valve function Chest radiograph; CTR	7	3	7	3	8	2
15 16177	Making decisions	-	8	3	-	-	-	-
16 17 18 19 20	Carrying out daily routine	-	8	2	-	-	-	-
21 22 23	Communicating with-receiving-spoken messages	FIM; Comprehension	8	2	8	1	8	1
24 25 26	Speaking	FIM; Expression	8	2	8	1	8	2
27 28 29	Transferring oneself	FIM; Transfers	8	1	8	1	8	1
30 31 32	Walking	FIM; Walk 5-m walk test	8	1	8	2	8	5
33 34 35	Washing oneself	FIM; Bathing	8	1	8	1	8	1
36 37 38	Caring for body parts	FIM; Grooming	7	1	8	2	7	1
39 40 41	Toileting	FIM; Toileting	7	2	9	2	7	3
42 43 44	Dressing	FIM; Dressing	8	1	8	1	8	1
45 46 47	Eating/ Drinking	FIM; Eating	8	1	8	2	8	3
48 49 50	Looking after one's health	-	8	3	-	-	-	-
51 52 53	Acquisition of goods and services	Instrumental Activities of Daily Living scale; Shopping	8	4	8	3	8	3
54 55 56	Preparing meals	Instrumental Activities of Daily Living scale; Food preparation	8	2	8	1	8	3
57 58 59	Doing housework	Instrumental Activities of Daily Living scale; Housekeeping	8	4	8	3	8	3
60	Basic interpersonal interactions	-	8	3	-	-	-	-
	Family relationships	-	8	3	-	-	-	-
	Recreation and leisure	-	8	2	-	-	-	-
	Immediate family	-	8	3	-	-	-	-
	Personal care providers and personal assistants	-	8	2	-	-	-	-
	Health professionals	-	8	1	-	-	-	-
	Individual attitudes of immediate	-	8	2	-	-	-	-

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6	family members							
7 8 9	General social support services, systems, and policies	-	8	2	-	-	-	-
10 11 12	Health services, systems, and policies	-	8	3	-	-	-	-

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

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317 DISCUSSION

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

326 The purpose of this study was to develop an assessment method that could be used
327 not only by cardiovascular physicians but also by medical professionals: home
328 physicians, care managers, and paramedical professions. Therefore, we adopted a
329 simple evaluation method that requires as little special machinery and environment as
330 possible. For example, although exercise tolerance at b455 has been reported to be a
331 prognostic factor for HF [49], we avoided the cardiopulmonary exercise testing (CPX)
332 and 6-minute walk test, and the specific activity scale (SAS) was chosen instead. [50-
333 54] We selected gait speed and FIM as the existing assessment batteries linked to the
334 d450 walking, but we selected only FIM for simplicity and ease of assessment at the
335 suggestion of the panel members in the second Delphi round. The ICF categories in this
336 study did not include renal function, BNP or anaemia, which are prognostic factors for
337 heart failure.[55] We suggest that these items be added, although the increase in the
338 items may prevent their wide-spread use in the clinical setting, making their clinical use
339 more difficult. In addition, the comprehensive ICF-based assessment of older patients
340 with HF developed in this study did not include personal factors such as age, gender,
341 values, lifestyle, coping strategies and personality.

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

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6 344 [57].

7 345 We propose that when using the ICF to share information on older people with HF across
8 346 multiple professions, it is necessary to include not only the 43 ICF categories, but also
9 347 personal factors.

10 348 In Japan, the establishment of a comprehensive community care system that integrates
11 349 medical care, welfare, and nursing care is being promoted, but evidence for information
12 350 sharing is lacking. We expect that the ICF-based assessment method for older patients
13 351 with HF developed in this study will be widely used in clinical practice.

14 352

15 353 **Strengths and limitations**

16 354 Since the purpose of this study was to develop a common community-based evaluation
17 355 method for medical and nursing care, we constructed an expert panel related to medical
18 356 professions and nursing care professions in Hiroshima prefecture. Since there is no
19 357 variation in the regions of the panel members, the existence of selective bias cannot be
20 358 denied. Therefore, we suggest that the results of this study should be used with caution
21 359 in regions other than Hiroshima prefecture. This study was based on the RAND/UCLS
22 360 Delphi method, but face-to-face meetings could not be conducted because of the current
23 361 coronavirus pandemic. Therefore, the implementation is not strictly based on the
24 362 RAND/UCLS method. We believe that we should have held an online meeting during the
25 363 Delphi Round 2. In this study, the Delphi method through expert consensus was used to
26 364 clarify the appropriateness of the evaluation method. The shortcomings of the Delphi
27 365 method are the possibility of coercion and inducement to gather opinions and the issue
28 366 of the validity of the questionnaire. In the future, it will be necessary to clarify the validity
29 367 of the evaluation method in survey studies of older patients with heart failure.

30 368

31 369 **Implications and Future directions**

32 370 The results of this study have two implications. First, it is the establishment of a
33 371 comprehensive assessment method for older patients with HF, which is a social problem
34 372 in Japan. Comprehensive multidisciplinary assessment is important to prevent
35 373 rehospitalization for HF, and the ICF-based scoring method developed in this study is
36 374 expected to prevent rehospitalization. Second, the ICF-based evaluation method allows
37 375 for an international comparison of the effectiveness of HF treatment and information
38 376 sharing. Wagner proposes a patient-centred model for chronic disease care that utilises
39 377 local social resources and information sharing systems such as information and
40 378 communication technology (ICT). [58,59] In the future, it is necessary to establish an
41 379 information sharing system using a comprehensive assessment method based on the

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6 380 ICF, and to examine the effect of readmission prevention and differences in life function
7 381 according to local policies.
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11 384 **CONCLUSION**

12
13 385 We developed a scoring method based on the ICF for older patients with HF and
14 386 clarified its appropriateness using the RAND/UCLA Delphi method. Future work is
15 387 required to develop an ICF-based information sharing system and to clarify its impact on
16 388 the prevention of re-hospitalisation and quality of life in older patients with HF.
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19 389

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37 401 **Contributions**

38 402 All authors meet the criteria for authorship of the ICMJE. SS, TK, TH and HK
39 403 contributed to the conceptualisation of the study. SS, NG, HF, SN, YT, NM, KK, MN
40 404 and MY were responsible for designing the questionnaire and collecting and analysing
41 405 the data. MN, MY, MM, HO and YY were responsible for recruiting the study
42 406 participants. YN, YK and HK were responsible for interpreting the results and managing
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56 414 **Competing interests**

57
58 415 The authors declare that there are no conflicts of interest regarding the publication of
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6 416 this paper.

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9 **418 Ethics approval**

10 419 The study was approved by the Hiroshima University of Epidemiological Research
11
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13 421

14
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19 **425 Data availability statement**

20 426 Data are available upon reasonable request.

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24 **428 Open access**

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8 621 [Kenkoukyoku-Soumuka/0000202651.pdf](https://www.mhlw.go.jp/file/05-Shingikai-10901000-Kenkoukyoku-Soumuka/0000202651.pdf) (Accessed 19 Nov 2021) 2018.
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20 629 59 Wagner EH, Austin BT, Davis C et al. Improving chronic illness care:
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6 632 **Figure Legends**
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8 633 Fig. 1: Development of Questionnaire and Delphi process flow
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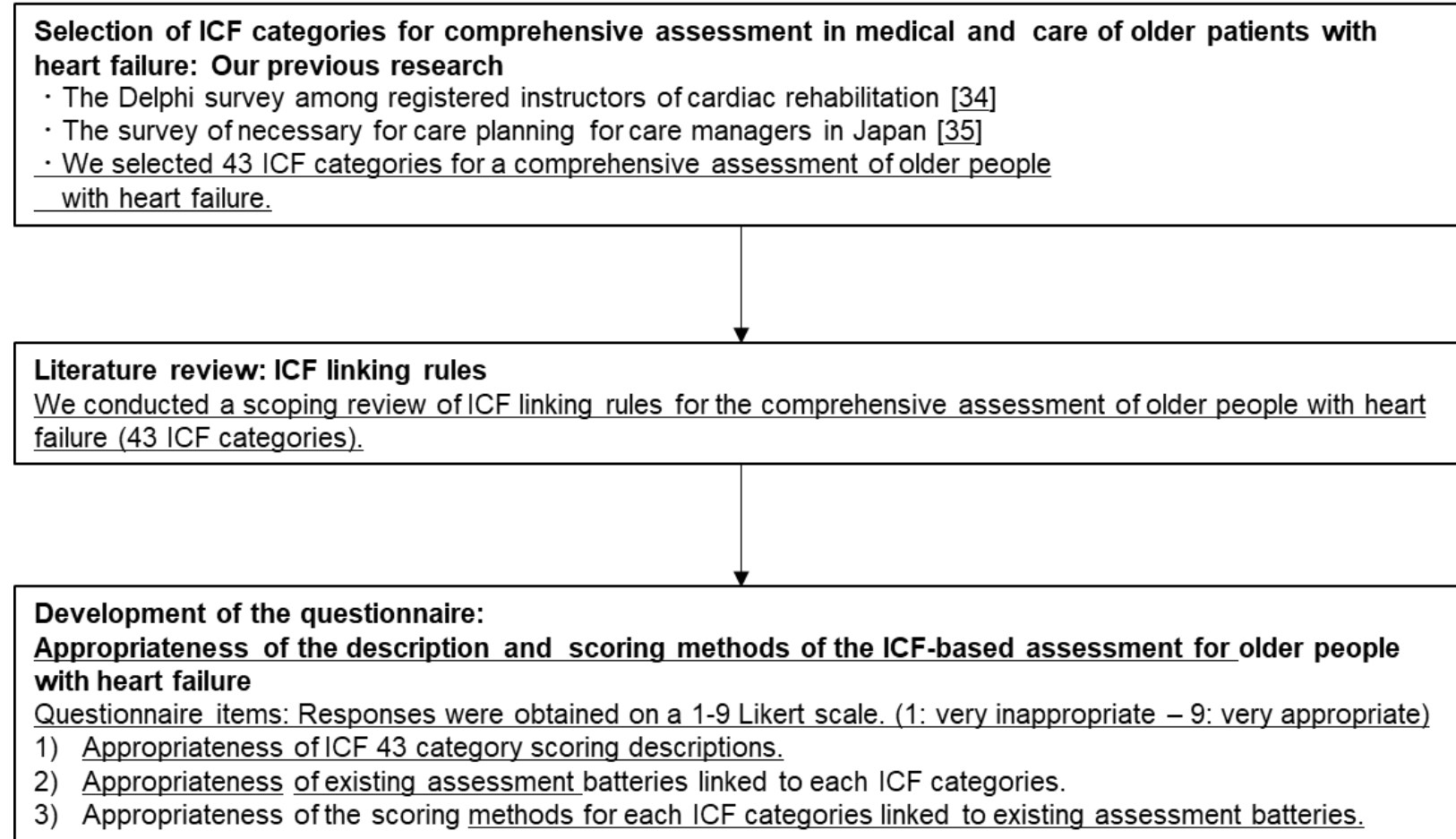
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13 635 Fig. 2: Selection of records and process flow diagrams
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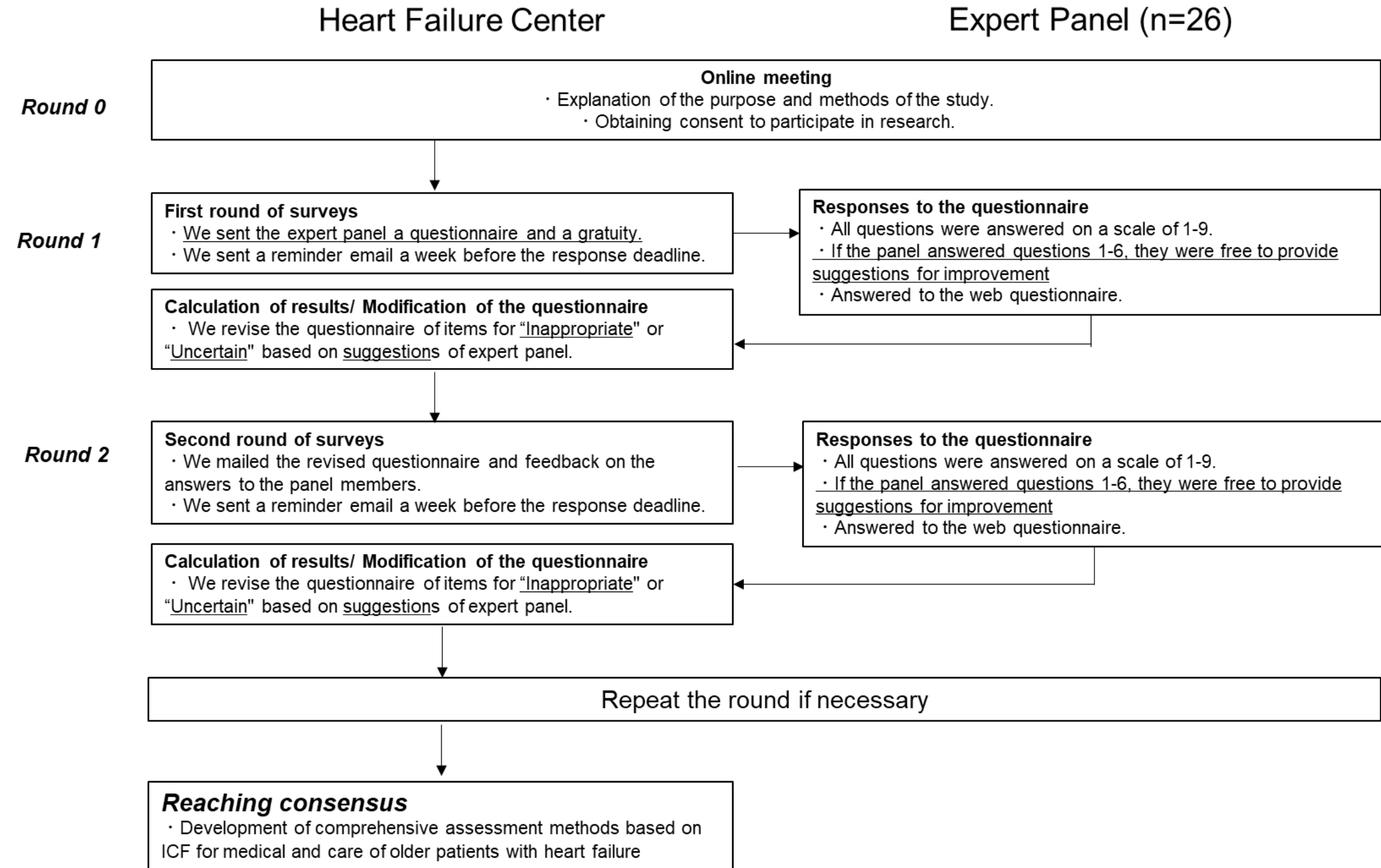
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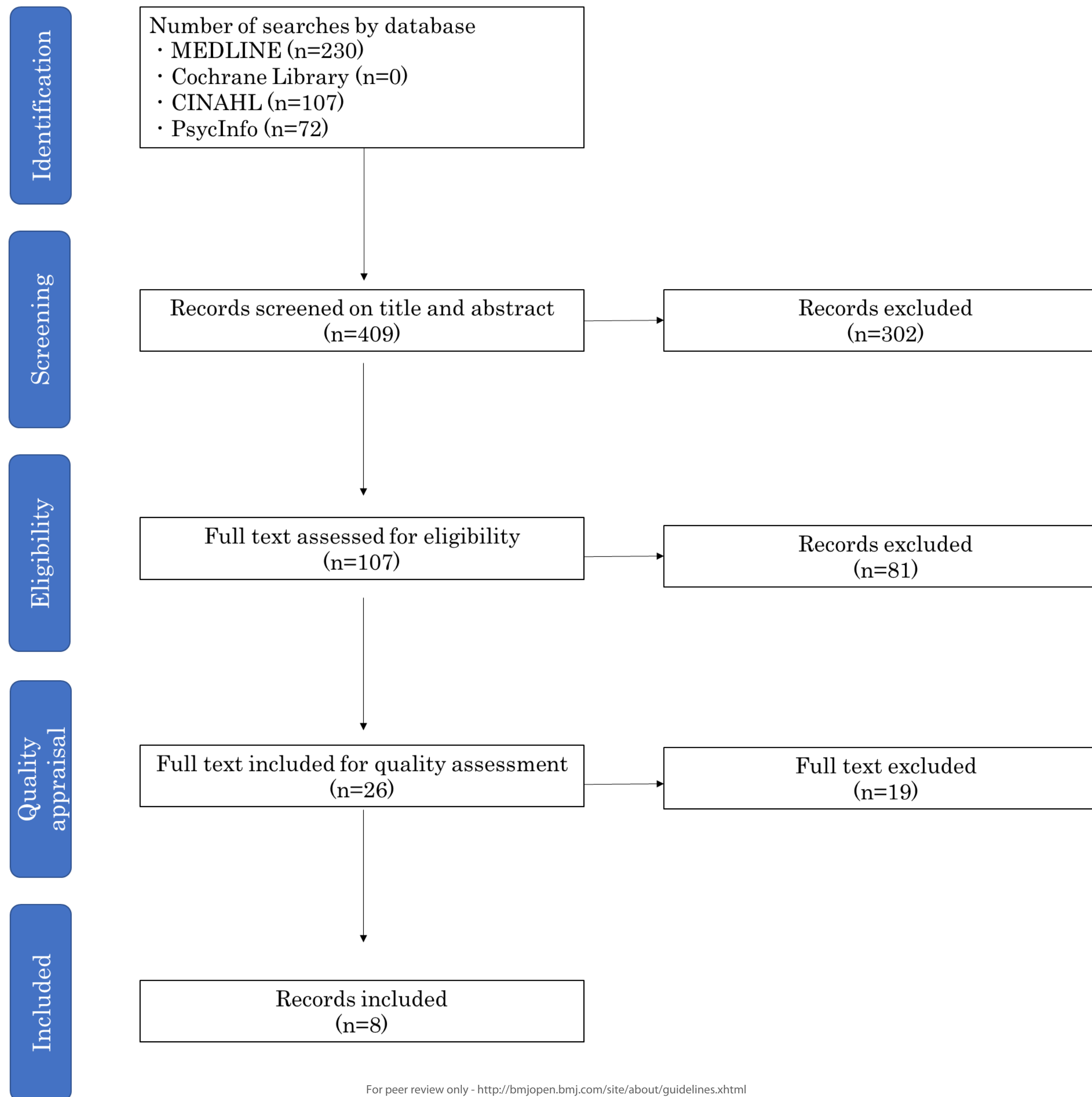
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Development of the questionnaire



Delphi approach





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 ($\geq 50\%$) 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)

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6 10: Easy eye-opening with a normal call.

7 20: Eyes open with loud voice or body shaking

8 30: Eyes open by repeated calls with pain stimulus.

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10 JCSIII(unarousable)

11 100: Movement to repel the pain stimulus.

12 200: Slight limb movement or frowning in response to the pain stimulus

13 300: Does not respond to pain stimulus

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16 **[Reference]**

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

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

22 3. Shigemori M, Abe T, Aruga T, et al. Guidelines for the Management of Severe Head Injury,
23 2nd edition guidelines from the Guidelines Committee on the Management of Severe Head
24 Injury, the Japan Society of Neurotraumatology. Neurol Med Chir 2012;52:1–30

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31 **Answer: Please tick the number that best applies**

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

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

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41 **Ratings**

42 0 No problem: JCS 0

43 1 Mild problem: JCS I -1 ~ JCS I -3

44 2 Moderate problem: JCS II -10 ~ JCS II -30

45 3 Severe problem: JCSIII-100 ~ JCSIII-200

46 4 Complete problem: JCSIII-300

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52 **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 ($\geq 50\%$) 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 ($\geq 50\%$) 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 ($\geq 50\%$) 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

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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		

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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 ($\geq 50\%$) 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

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6 Frontal Assessment Battery in patients with the frontal variant of frontotemporal dementia.
7 Psychiatry Clin Neurosci. 2007 Feb;61(1):78-83. doi: 10.1111/j.1440-1819.2007.01614.x.
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10 **Answer: Please tick the number that best applies**

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

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16 **3) Appropriateness of the scoring methods for b164 Higher-level cognitive functions**
17 **linked to Frontal Assessment Battery**
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21 **Ratings**

- 22 0 No problem: FAB Total scores 18-16
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24 1 Mild problem: FAB Total scores 15-14
25
26 2 Moderate problem: FAB Total scores 13-9
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28 3 Severe problem: FAB Total scores 8-5
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30 4 Complete problem: FAB Total scores 4-0

31 **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.

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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]					Prodinge B, et al (2019) [47]		Alarcos Cieza (2008) [45]	Bladh S, et al (2013) [41]				Prodinge B, et al (2017) [40]	
Assessment batteries	FIM	SF-36	EQ-5D	SF-36	EQ-5D	SF-36	NHP	WHOD AS 2.0	WHOQ OL-CHEF	WHOD AS 2.0	SF-36	SF-36	FES-I	FES(S)	ABC	SAFFE	FIM	Birthe Index
b110																		
b114																		
b130		✓		✓			✓		✓			✓						
b134							✓		✓									
b164																		
b410																		
b415																		
b420																		
b440																		
b455																		
b460																		
b525	✓																	
b530																		
b540																		
b620	✓																	
b710																		
b730																		
s410																		

1	d177																	
2	d230			✓	✓	✓		✓	✓									
3	d310							✓										
4	d330																	
5	d330																	
6	d420			✓						✓								
7	d420			✓						✓								
8	d450	✓		✓	✓	✓	✓	✓				✓		✓	✓	✓	✓	✓
9	d450	✓		✓	✓	✓	✓	✓				✓		✓	✓	✓	✓	✓
10	d510	✓		✓	✓	✓		✓		✓			✓	✓		✓		✓
11	d520	✓								✓								
12	d520	✓								✓								
13	d530	✓								✓			✓			✓	✓	
14	d540	✓		✓	✓	✓	✓	✓				✓	✓			✓	✓	
15	d540	✓		✓	✓	✓	✓	✓				✓	✓			✓	✓	
16	d550	✓						✓										✓
17	d560	✓																
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20	d620									✓			✓	✓		✓		
21	d620									✓			✓	✓		✓		
22	d630							✓		✓			✓			✓		
23	d630							✓		✓			✓			✓		
24	d640			✓	✓			✓				✓	✓	✓	✓			
25	d710																	
26	d760			✓	✓	✓												
27	d760			✓	✓	✓												
28	d920			✓	✓	✓	✓	✓	✓			✓				✓		
29	d920			✓	✓	✓	✓	✓	✓			✓				✓		
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31	e340																	
32	e340																	
33	e355																	
34	e410																	
35	e410																	
36	e575																	
37	e575																	
38	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)

1 Falls Efficacy Scale-International (FES-I), the Swedish version of the Falls Efficacy Scale (FES[S]), the Activities-specific Balance Confidence Scale (ABC),
2 the modified Survey of Activities and Fear of Falling in the Elderly (SAFFE)
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Supplemental material 3

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

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)
110	Consciousness function	Japan Coma Scale	7	7	8	1	7	4
114	Orientation function	Mimi-Mental State Examination	8	6	8	2	8	4
130	Energy and drive function	Vitality Index	7	7	8	2	8	2
134	Sleep function	-	7	9	-	-	-	-
164	Higher-level cognitive functions	Frontal Assessment Battery	7	6	7	7	7.5	4
410	Heart function	Echocardiography; left ventricular function, Electrocardiogram	7	4	7	8	7	11
415	Blood vessel function	Fontaine classification	7	5	8	2	8	4
420	Blood pressure function	Blood pressure	7	6	7.5	4	8	4
440	Respiration function	Arterial Blood Gas Analysis, fraction of inspiratory oxygen, SpO ₂ , Respiration Rate	8	4	8	4	7	5
455	Exercise tolerance function	Specific Activity Scale	8	3	7.5	1	7	3
460	Sensations associated with cardiovascular and respiratory functions	NYHA classification	8	4	8	3	8	2
525	Defaecation function	-	7	6	7	4	-	-
530	Weight maintenance functions	Body Mass Index	7	6	8	3	8	4
545	Water, mineral and electrolyte balance functions	Blood test: Na, K	7.5	5	8	4	7.5	6

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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	-	-	-	-

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6 7 8 9 10 11 12 13 14	Individual attitudes of immediate family members	-	7.5	5	-	-	-	-
9 10 11 12 13 14	General social support services, systems, and policies	-	7.5	5	-	-	-	-
12 13 14	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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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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6 1 Original research

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9 3 **Development and appropriateness of a scoring method for International**
10 4 **Classification of Functioning, Disabilities, and Health assessment in older patients**
11 5 **with heart failure: a Delphi survey of expert panel in Japan**

12 6
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34 **ABSTRACT**

35 **Objective:** The number of older patients with heart failure (HF) is increasing in Japan
36 and has become a social problem. There is an urgent need to develop a comprehensive
37 assessment methodology based on the common language of health care; the
38 International Classification of Functioning, Disability and Health (ICF). The purpose of
39 this study was to develop and confirm the appropriateness of a scoring methodology for
40 43 ICF categories in older people with HF.

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

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

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

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

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

61
62 **Keywords:** heart failure, older people, ICF, scoring methods, RAND/UCLA
63 Appropriateness Method

64 **Strengths and limitations of this study**

65 **►** An expert panel familiar with heart failure care, consisting of home physicians, care
66 managers, and multidisciplinary medical professionals, rated the "appropriateness" of
67 the questions in each ICF category through a multiple-round process to reach a
68 consensus.
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6 70 ▶ The assessment domains studied the 43-item ICF relevant to older adults with heart
7 71 failure, covering not only the medical assessment but also the physical and mental
8 72 functioning, activity and social participation, and environmental factors.
9
10 73 ▶The expert panel comprised general practitioners, cardiologists, and paramedical
11 74 professions (rehabilitation, nursing care, and welfare), but caution is needed in
12 75 generalizing the findings because of the study's limited geographical area.
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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

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6 113 World Health Organisation provides the ICF Core Set and the ICF Linking Rules. The
7 114 ICF Core Set is a set of identified ICF categories for assessing a patient's special health
8 115 condition or special medical background. [29] The ICF Linking Rules are a method of
9 116 linking ICF categories with existing assessment methods. [30,31] The ICF core set for
10 117 chronic ischaemic heart disease and the Geriatric ICF core set have already been
11 118 developed, but these ICF categories are not appropriate for adaptation to older patients
12 119 with heart failure. [32,33] Therefore, 43 ICF categories were selected for the
13 120 comprehensive assessment of older patients with HF through the questionnaire survey
14 121 of a multidisciplinary group of medical professionals and care professionals. [34,35] The
15 122 43 ICF categories specific to older patients with HF consisted of 17 body functions and
16 123 one body structure, 19 activities and participation, and 6 environmental factors. However,
17 124 in order to efficiently utilize ICF-based assessments in clinical practice, it is necessary to
18 125 develop scoring methods linked to existing assessments.

19 126 The purpose of this study was to develop a scoring method of older patients with HF
20 127 based on the ICF, and to determine its appropriateness using the Delphi technique.
21 128

22 129 **METHOD**

23 130 **Patient and public involvement**

24 131 Patients and the public are not involved in the design, planning, conduct or reporting of
25 132 this study.
26 133

27 134 **Design**

28 135 We applied the Delphi method to an expert panel. The Delphi method is a consensus
29 136 method used in the development of guidelines and clinical indicators, and is effective in
30 137 guiding assessments and treatments for which there is limited evidence. The Delphi
31 138 method is also a standard practice in the development of ICF Core Sets. [29] We
32 139 developed a questionnaire based on the literature review and structured a two-stage
33 140 Delphi survey with an expert panel, referring to the RAND/UCLA appropriateness
34 141 methodology. [36] (Figure 1).
35 142

36 143 **Establishing of the expert panel**

37 144 We established an expert multidisciplinary panel consisting of 26 medical and care
38 145 professionals in Hiroshima Prefecture, Japan. The members of the expert committee
39 146 were professionals with leadership roles in community care, all of whom have expertise
40 147 in the assessment, treatment, and care of older patients with heart failure. Five home
41 148 physicians and ten care managers were recommended by the Hiroshima Care Manager

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6 149 Association. All five home physicians are specialists in internal medicine who engage in
7 150 home visits while all ten care managers are board members of the Hiroshima Care
8 151 Manager Association and leaders in their respective communities. In addition, we
9 152 included 11 medical multidisciplinary professionals involved in HF care at specialised
10 153 medical institutions recommended by the Hiroshima Heart Health Promotion Project in
11 154 our panel .[37] The 11 medical multidisciplinary members were: two cardiovascular
12 155 physicians, three nurses certified in chronic HF nursing, two physiotherapists with
13 156 registered instructors of cardiac rehabilitation, one occupational therapist with registered
14 157 instructors of cardiac rehabilitation, one certified pharmacist, one nutritionist, and one
15 158 social worker.
16 159

160 **Development of the questionnaire**

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

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6 185 existing assessment batteries linked to each ICF categories, and 3) appropriateness of
7 186 the scoring methods for each ICF categories linked to existing assessment batteries. All
8 187 questionnaires were developed using a Google Form, with a description of each ICF
9 188 category and the rationale for scoring. (Supplemental materials 1).
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190 **Delphi process and funding consensus**

191 The Delphi process for reaching a consensus is shown in Figure 1. Following the
192 RAND/UCLA appropriateness methodology [28], we used the median scores of the
193 responses from the panellists to assess appropriateness. We rated the appropriateness
194 of the 43 ICF categories as 'Appropriate' if the median respondent's score was from 7–
195 9, 'Uncertain' if it was from 4–6, and 'Inappropriate' if it was from 1–3. In accordance with
196 the RAND/UCLA guidelines, we defined 'Agreement' or 'Disagreement' according to the
197 number of panellists who rated outside the range of the tertiles (1–3; 4–6; 7–9), including
198 the median. 'Agreement' was defined as fewer than one-third of panellists rating outside
199 the range of the tertile values, whereas 'Disagreement' was defined as more than one-
200 third of panellists rating the extremes (1–3 range and 7–9 range), not including the
201 median.

202 Before conducting the Delphi survey, the HF Centre (HFC) held an online meeting for
203 the panel members. In the online meeting, we explained the purpose of our study and
204 the methods of the Delphi process to the panel members and obtained their consent to
205 participate in the study. In the first round, the HFC mailed a sheet with instructions on
206 how to conduct the ICF category adequacy assessment, as well as the URL and QR
207 codes for the questionnaire. The panel members responded to three questions in 43 ICF
208 categories on a scale of 1-9. In addition, panel members provided open-ended
209 suggestions for improvements to the questions they scored 1-6. The HFC collated the
210 panel members' responses. We revised the scoring descriptions and existing
211 assessment batteries linked to the ICF categories responded to as 'Inappropriate',
212 'Uncertain' or 'Disagreement' based on the panel's suggestions. In the second round,
213 the HFC emailed the revised questionnaire and feedback based on the panel members'
214 responses. As in the first round, panel members again scored the appropriateness of
215 three of the question items in all 43 ICF categories. In addition, the panel members
216 provided suggestions for improvements to the scoring methods on those ones scored
217 1-6.

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

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

222

223 **Analysis**

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

226

227 **Ethics**

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

236

237 **RESULTS**

238 **Characteristics of the expert panel participants**

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

243

244 Table 1 Characteristics of the expert panel participants who responded to all Delphi
245 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)

246 247 **Development of the Delphi questionnaire of ICF assessment method for older** 248 **patients with heart failure**

249 Figure 2 showed the process of literature review. Following a two-stage screening
250 process, we conducted a qualitative analysis of 26 references. In the qualitative analysis,
251 we excluded 19 references dealing with disease-specific assessment batteries that could
252 not be adapted to older patients with HF (e.g., stroke, musculoskeletal disease, hand
253 surgery, low back pain). Eight articles on ICF linking rules were included. Finally, we
254 employed 11 existing assessment batteries on eight articles links to the 43 ICF
255 categories (Supplemental material 2). [40-47] Eleven existing assessment batteries were
256 included: assessment of ADL (such as Functional Independence Measure (FIM) and
257 Barthel Index), assessment of general health-related quality of life (such as Short Form
258 36 and the European Quality of Life instrument (EQ-5D), The World Health Organization
259 Quality of Life (WHOQOL)), assessment of general health status (such as the
260 Nottingham Health Profile(NHP), the World Health Organization Disability Assessment
261 Schedule (WHODAS 2.0)), and assessment of falls (such as Falls Efficacy Scale-
262 International (FES-I), the Swedish version of the Falls Efficacy Scale (FES[S]), the
263 Activities-specific Balance Confidence Scale (ABC), and the modified Survey of Activities
264 and Fear of Falling in the Elderly (SAFFE)). We identified these existing assessment
265 batteries as linked to 20 of the 43 categories. However, we included only the FIM and
266 the BI. We did not include assessment batteries for general health-related quality of life,
267 general health status, and falls in the questionnaire because these were not consistent
268 with the aims of this study.

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

274 **Delphi round 1**

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

293 **Delphi round 2**

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

309 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)
7110	Consciousness function	Japan Coma Scale	8	3	9	2	8	1
6114	Orientation function	Mimi-Mental State Examination	8	3	8	4	8	2
6130	Energy and drive function	Vitality Index	8	2	8	3	8	2
6134	Sleep function	Pittsburgh Sleep Quality Index	8	2	8	2	7	4
6164	Higher-level cognitive functions	Frontal Assessment Battery	8	2	8	2	8	3
6410	Heart function	Echocardiography; left ventricular function, Electrocardiogram	7	4	8	3	7	3
6415	Blood vessel function	Fontaine classification	8	4	8	2	8	4
6420	Blood pressure function	Blood pressure	8	4	8	1	8	2
6440	Respiration function	SpO ₂ , Respiration Rate	8	2	8	3	8	1
6455	Exercise tolerance function	Specific Activity Scale	8	2	8	3	8	1
6460	Sensations associated with cardiovascular and respiratory functions	NYHA classification	8	2	8	1	9	1
6525	Defaecation function	-	8	3	-	-	-	-
6530	Weight maintenance functions	Body Mass Index	8	3	8	3	8	3
6545	Water, mineral and electrolyte balance functions	Blood test: Na, K	8	4	8	3	7	3
6620	Urination function	-	8	4	-	-	-	-
6710	Mobility of joint function	Range Of Motion	8	3	8	3	8	2
6730	Muscle power function	Manual Muscle Test or five-times	8	3	8	3	8	4

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5		sit-to-stand							
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7	Structure of the cardiovascular system	Echocardiography; Severity of valve function Chest radiograph; CTR	7	3	7	3	8	2	
8									
9	410								
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11	177	Making decisions	-	8	3	-	-	-	-
12	230	Carrying out daily routine	-	8	2	-	-	-	-
13									
14	310	Communicating with-receiving-spoken messages	FIM; Comprehension	8	2	8	1	8	1
15									
16	330	Speaking	FIM; Expression	8	2	8	1	8	2
17									
18	420	Transferring oneself	FIM; Transfers	8	1	8	1	8	1
19									
20	450	Walking	FIM; Walk 5-m walk test	8	1	8	2	8	5
21									
22	510	Washing oneself	FIM; Bathing	8	1	8	1	8	1
23									
24	520	Caring for body parts	FIM; Grooming	7	1	8	2	7	1
25									
26	530	Toileting	FIM; Toileting	7	2	9	2	7	3
27									
28	540	Dressing	FIM; Dressing	8	1	8	1	8	1
29									
30	550/ 31	Eating/ Drinking	FIM; Eating	8	1	8	2	8	3
31									
32	570	Looking after one's health	-	8	3	-	-	-	-
33									
34	620	Acquisition of goods and services	Instrumental Activities of Daily Living scale; Shopping	8	4	8	3	8	3
35									
36	630	Preparing meals	Instrumental Activities of Daily Living scale; Food preparation	8	2	8	1	8	3
37									
38	640	Doing housework	Instrumental Activities of Daily Living scale; Housekeeping	8	4	8	3	8	3
39									
40	710	Basic interpersonal interactions	-	8	3	-	-	-	-
41									
42	760	Family relationships	-	8	3	-	-	-	-
43									
44	920	Recreation and leisure	-	8	2	-	-	-	-
45									
46	310	Immediate family	-	8	3	-	-	-	-
47									
48	340	Personal care providers and personal assistants	-	8	2	-	-	-	-
49									
50	355	Health professionals	-	8	1	-	-	-	-
51									
52	410	Individual attitudes of immediate family members	-	8	2	-	-	-	-
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54	575	General social support services,	-	8	2	-	-	-	-
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6	systems, and policies							
7 8 9	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

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6 344 multiple professions, it is necessary to include not only the 43 ICF categories, but also
7 345 personal factors.

8 346 In Japan, the establishment of a comprehensive community care system that integrates
9 347 medical care, welfare, and nursing care is being promoted, but evidence for information
10 348 sharing is lacking. We expect that the ICF-based assessment method for older patients
11 349 with HF developed in this study will be widely used in clinical practice.
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351 **Strengths and limitations**

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

368 The results of this study have two implications. First, it is the establishment of a
369 comprehensive assessment method for older patients with HF, which is a social problem
370 in Japan. Comprehensive multidisciplinary assessment is important to prevent
371 rehospitalization for HF, and the ICF-based scoring method developed in this study is
372 expected to prevent rehospitalization. Second, the ICF-based evaluation method allows
373 for an international comparison of the effectiveness of HF treatment and information
374 sharing. Wagner proposes a patient-centred model for chronic disease care that utilises
375 local social resources and information sharing systems such as information and
376 communication technology (ICT). [58,59] In the future, it is necessary to establish an
377 information sharing system using a comprehensive assessment method based on the
378 ICF, and to examine the effect of readmission prevention and differences in life function
379 according to local policies.
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8 382 **CONCLUSION**

9 383 We developed a scoring method based on the ICF for older patients with HF and
10 384 clarified its appropriateness using the RAND/UCLA Delphi method. Future work is
11 385 required to develop an ICF-based information sharing system and to clarify its impact on
12 386 the prevention of re-hospitalisation and quality of life in older patients with HF.

13 387

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24 398

25 399 **Contributions**

26 400 All authors meet the criteria for authorship of the ICMJE. SS, TK, TH and HK
27 401 contributed to the conceptualisation of the study. SS, NG, HF, SN, YT, NM, KK, MN
28 402 and MY were responsible for designing the questionnaire and collecting and analysing
29 403 the data. MN, MY, MM, HO and YY were responsible for recruiting the study
30 404 participants. YN, YK and HK were responsible for interpreting the results and managing
31 405 the project. SS and HK supervised all research activities. All authors reviewed the
32 406 current draft and approved the final current submission.

33 407

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37 411

38 412 **Competing interests**

39 413 The authors declare that there are no conflicts of interest regarding the publication of
40 414 this paper.

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416 **Ethics approval**

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

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420 **Provenance and peer review**

421 Not commissioned; externally peer reviewed.

422

423 **Data availability statement**

424 No additional data available.

425

426 **Open access**

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8 619 [Kenkoukyoku-Soumuka/0000202651.pdf](https://www.mhlw.go.jp/file/05-Shingikai-10901000-Kenkoukyoku-Soumuka/0000202651.pdf) (Accessed 19 Nov 2021) 2018.
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6 630 **Figure Legends**
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8 631 Fig. 1: Development of Questionnaire and Delphi process flow
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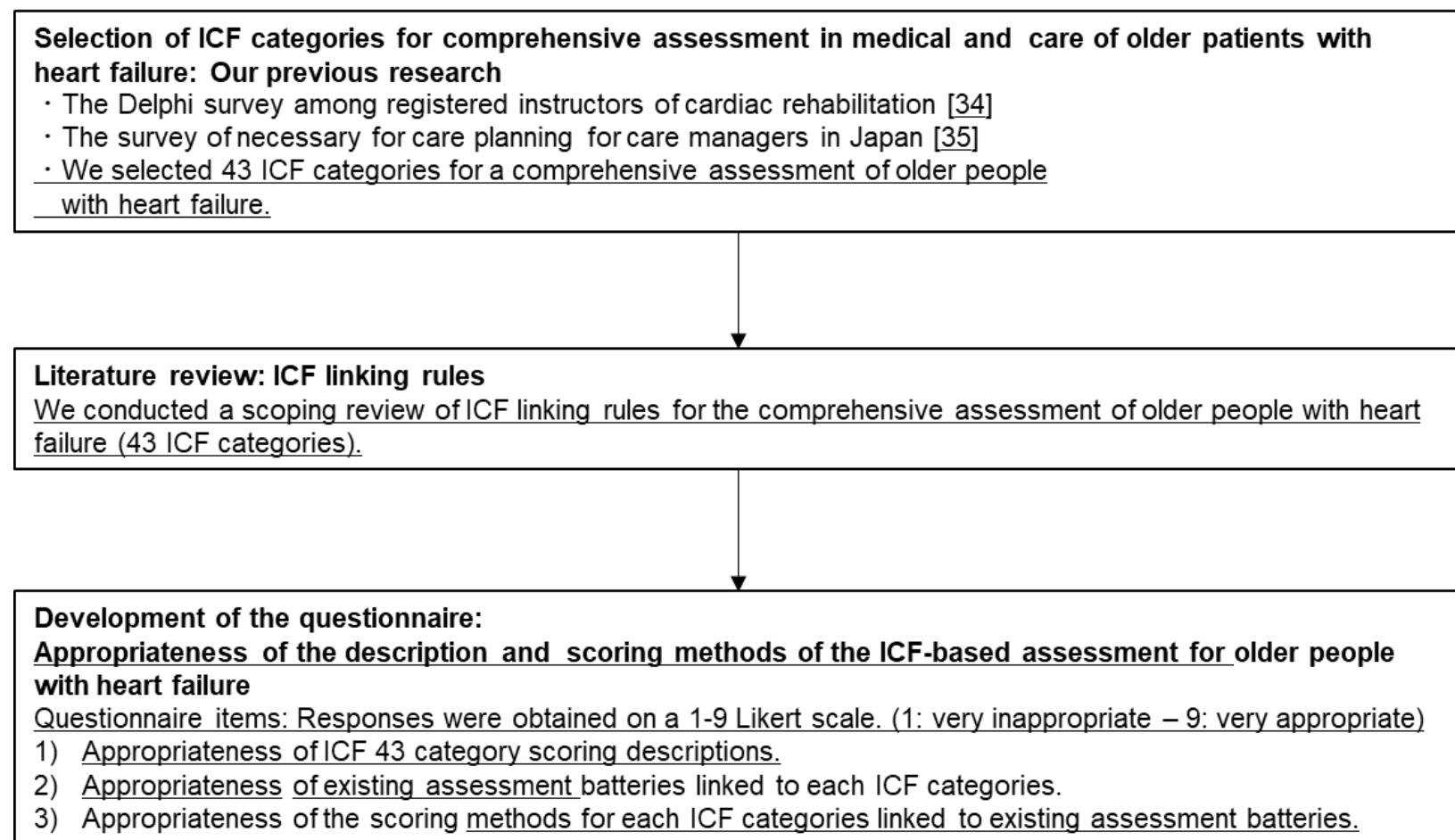
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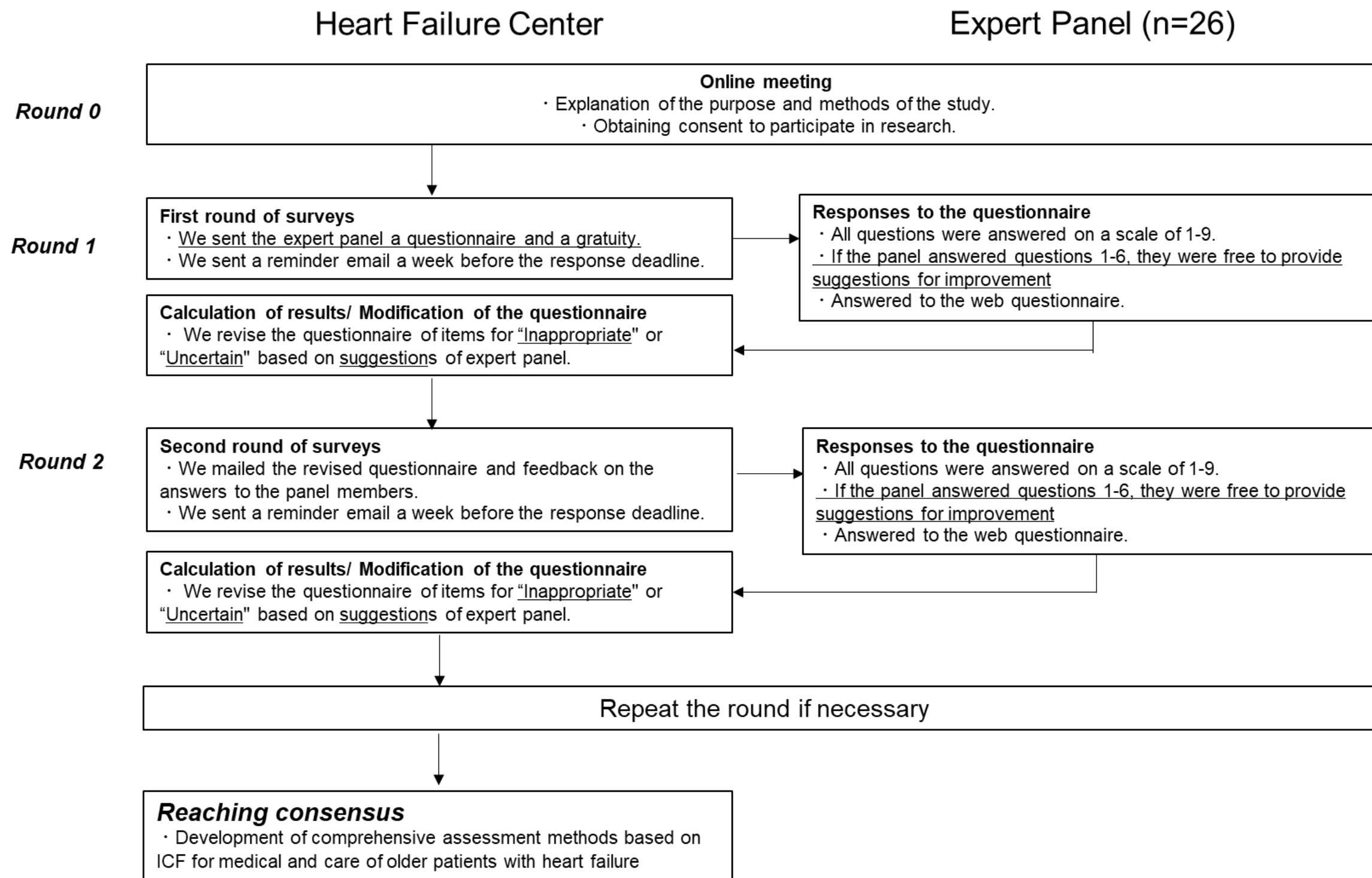
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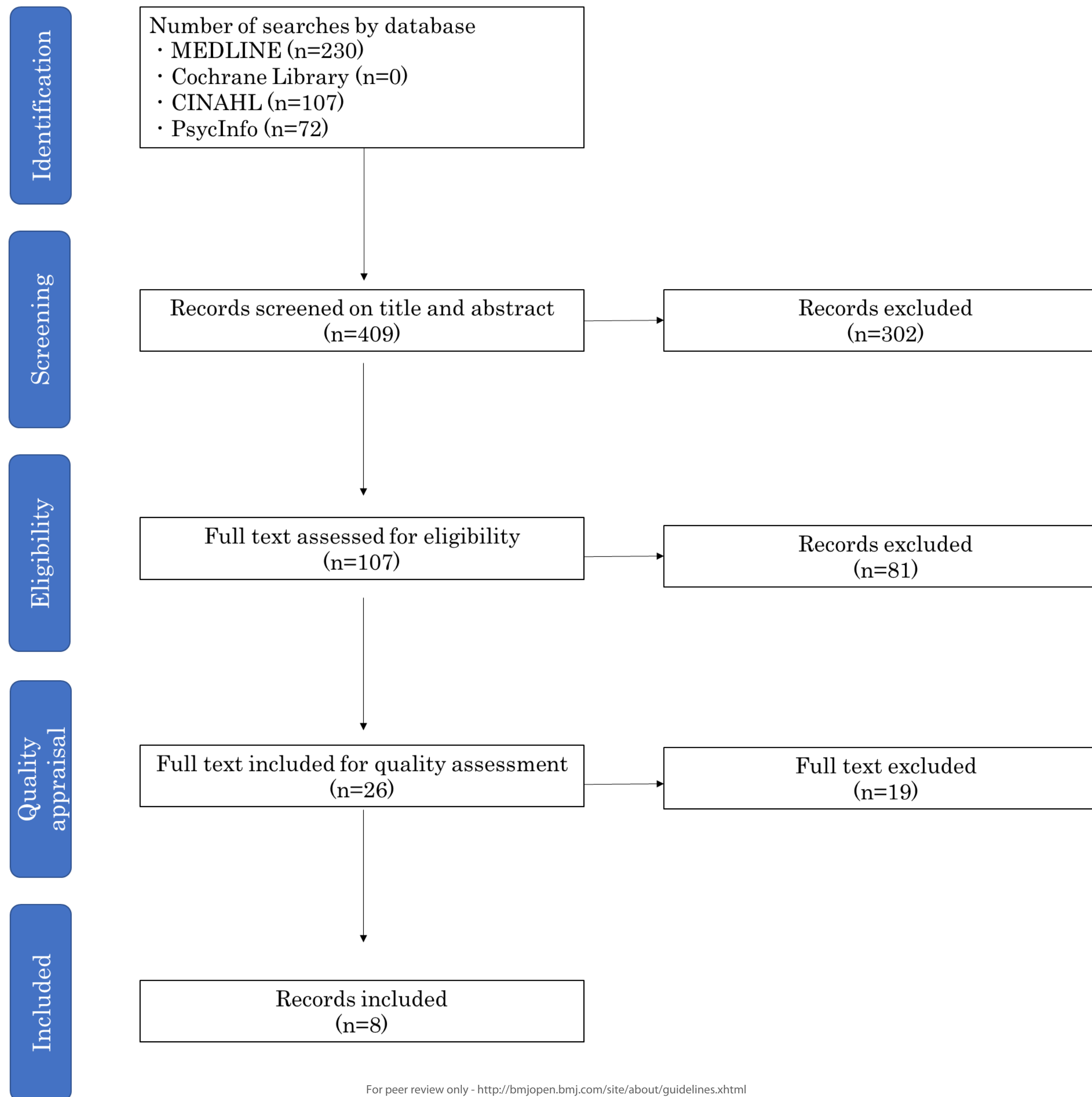
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Development of the questionnaire



Delphi approach





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 ($\geq 50\%$) 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)

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6 10: Easy eye-opening with a normal call.

7 20: Eyes open with loud voice or body shaking

8 30: Eyes open by repeated calls with pain stimulus.

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10 JCSIII(unarousable)

11 100: Movement to repel the pain stimulus.

12 200: Slight limb movement or frowning in response to the pain stimulus

13 300: Does not respond to pain stimulus

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16 **[Reference]**

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

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

22 3. Shigemori M, Abe T, Aruga T, et al. Guidelines for the Management of Severe Head Injury,
23 2nd edition guidelines from the Guidelines Committee on the Management of Severe Head
24 Injury, the Japan Society of Neurotraumatology. Neurol Med Chir 2012;52:1–30

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31 **Answer: Please tick the number that best applies**

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

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

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41 **Ratings**

42 0 No problem: JCS 0

43 1 Mild problem: JCS I -1 ~ JCS I -3

44 2 Moderate problem: JCS II -10 ~ JCS II -30

45 3 Severe problem: JCSIII-100 ~ JCSIII-200

46 4 Complete problem: JCSIII-300

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52 **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 ($\geq 50\%$) 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 ($\geq 50\%$) 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 ($\geq 50\%$) 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

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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		

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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 ($\geq 50\%$) 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

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6 Frontal Assessment Battery in patients with the frontal variant of frontotemporal dementia.
7 Psychiatry Clin Neurosci. 2007 Feb;61(1):78-83. doi: 10.1111/j.1440-1819.2007.01614.x.
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10 **Answer: Please tick the number that best applies**

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

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16 **3) Appropriateness of the scoring methods for b164 Higher-level cognitive functions**
17 **linked to Frontal Assessment Battery**
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21 **Ratings**

- 22 0 No problem: FAB Total scores 18-16
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24 1 Mild problem: FAB Total scores 15-14
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26 2 Moderate problem: FAB Total scores 13-9
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28 3 Severe problem: FAB Total scores 8-5
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30 4 Complete problem: FAB Total scores 4-0

31 **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.

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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]					Prodinge B, et al (2019) [47]		Alarcos Cieza (2008) [45]	Bladh S, et al (2013) [41]				Prodinge B, et al (2017) [40]	
Assessment batteries	FIM	SF-36	EQ-5D	SF-36	EQ-5D	SF-36	NHP	WHOD AS 2.0	WHOQ OL-CHEF	WHOD AS 2.0	SF-36	SF-36	FES-I	FES(S)	ABC	SAFFE	FIM	Birthe Index
b110																		
b114																		
b130		✓		✓			✓		✓			✓						
b134							✓		✓									
b164																		
b410																		
b415																		
b420																		
b440																		
b455																		
b460																		
b525	✓																	
b530																		
b540																		
b620	✓																	
b710																		
b730																		
s410																		

1	d177																	
2	d230			✓	✓	✓		✓	✓									
3	d310							✓										
4	d330																	
5	d330																	
6	d420			✓						✓								
7	d420			✓						✓								
8	d450	✓		✓	✓	✓	✓	✓				✓		✓	✓	✓	✓	✓
9	d450	✓		✓	✓	✓	✓	✓				✓		✓	✓	✓	✓	✓
10	d510	✓		✓	✓	✓		✓		✓			✓	✓		✓		✓
11	d520	✓								✓								
12	d520	✓								✓								
13	d530	✓								✓			✓			✓	✓	
14	d540	✓		✓	✓	✓	✓	✓				✓	✓			✓	✓	
15	d540	✓		✓	✓	✓	✓	✓				✓	✓			✓	✓	
16	d550	✓						✓										✓
17	d560	✓																
18	d560	✓																
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21	d620									✓			✓	✓		✓		
22	d630							✓		✓			✓			✓		
23	d630							✓		✓			✓			✓		
24	d640			✓	✓			✓				✓	✓	✓	✓			
25	d710																	
26	d760			✓	✓	✓												
27	d760			✓	✓	✓												
28	d920			✓	✓	✓	✓	✓	✓			✓				✓		
29	d920			✓	✓	✓	✓	✓	✓			✓				✓		
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31	e340																	
32	e340																	
33	e355																	
34	e410																	
35	e410																	
36	e575																	
37	e575																	
38	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)

1 Falls Efficacy Scale-International (FES-I), the Swedish version of the Falls Efficacy Scale (FES[S]), the Activities-specific Balance Confidence Scale (ABC),
2 the modified Survey of Activities and Fear of Falling in the Elderly (SAFFE)
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Supplemental material 3

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

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			
Existing assessment batteries linked to ICF categories			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)		
10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29	30	110	Consciousness function	Japan Coma Scale	7	7	8	1	7	4
31 32	31	114	Orientation function	Mimi-Mental State Examination	8	6	8	2	8	4
33	33	130	Energy and drive function	Vitality Index	7	7	8	2	8	2
34 35	34	134	Sleep function	-	7	9	-	-	-	-
36	36	164	Higher-level cognitive functions	Frontal Assessment Battery	7	6	7	7	7.5	4
37 38 39	38	410	Heart function	Echocardiography; left ventricular function, Electrocardiogram	7	4	7	8	7	11
40 41	40	415	Blood vessel function	Fontaine classification	7	5	8	2	8	4
42	42	420	Blood pressure function	Blood pressure	7	6	7.5	4	8	4
43 44 45 46 47	44	440	Respiration function	Arterial Blood Gas Analysis, fraction of inspiratory oxygen, SpO ₂ , Respiration Rate	8	4	8	4	7	5
48 49	48	455	Exercise tolerance function	Specific Activity Scale	8	3	7.5	1	7	3
50 51 52 53	50	460	Sensations associated with cardiovascular and respiratory functions	NYHA classification	8	4	8	3	8	2
54 55	54	525	Defaecation function	-	7	6	7	4	-	-
56	56	530	Weight maintenance functions	Body Mass Index	7	6	8	3	8	4
57 58 59	57	545	Water, mineral and electrolyte balance functions	Blood test: Na, K	7.5	5	8	4	7.5	6

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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	-	-	-	-

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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.