Development and Practical Test of Quality Indicators for Palliative Care in Patients With Chronic Heart Failure

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Background: Palliative care is highly relevant for patients with heart failure (HF), and there is a need for quantitative information on quality of care. Accordingly, this study aimed to develop a set of quality indicators (QIs) for palliative care of HF patients, and to conduct a practical pilot measurement of the proposed QIs in clinical practice.

Methods and Results: We used a modified Delphi technique, a consensus method that involves a comprehensive literature review, face-to-face multidisciplinary panel meeting, and anonymous rating in 2 rounds. A 15-member multidisciplinary expert panel individually rated each potential indicator on a scale of 1 (lowest) to 9 (highest) for appropriateness. All indicators receiving a median score ≥7 without significant disagreement were included in the final set of QIs. Through the consensus-building process, 35 QIs were proposed for palliative care in HF patients. Practical measurement in HF patients (n=131) from 3 teaching hospitals revealed that all of the proposed QIs could be obtained retrospectively from medical records, and the following QIs had low performance (<10%): “Intervention by multidisciplinary team”, “Opioid therapy for patients with refractory dyspnea”, and “Screening for psychological symptoms”.

Conclusions: The first set of QIs for palliative care of HF patients was developed and could clarify quantitative information and might improve the quality of care.

Key Words: Heart failure; Palliative care; Quality indicators

Heart failure (HF) is a progressive disease and a major growing public health problem worldwide.1 As Japan becomes a super-aging society, the number of HF patients is dramatically increasing.2 In the course of HF, patients typically experience debilitating physical and emotional symptoms, all of which severely degrade quality of life (QoL).3,4 Palliative care is a multidisciplinary approach to improving symptoms and QoL,5 and is considered to be highly relevant for HF patients.6 However, its application in HF patients has been underutilized and suboptimal. For the implementation of palliative care for HF patients, there is a need to understand the standard concepts and methods of palliative care. In addition, illness trajectory and disease management of HF are different from those of cancer. Thus, deliberative palliative care systems specific to HF patients should be created.

Quality indicators (QIs) are measurable elements of practice performance for which there is evidence or consensus and can highlight and reveal quality issues.7 In the field of

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cancer, QIs for palliative care have been reviewed and updated regularly, which is useful for understanding the current standard concept and detailed methods of palliative care. It is also useful for creating and improving palliative care systems. However, there are limited reports on QIs for palliative care of HF patients.

Our objectives are to promote palliative care for HF patients, to make the quality of care even and equal across the medical settings and to improve the practice of palliative care. Accordingly, the present study aimed to propose a set of QIs for palliative care in HF patients based on a comprehensive review and panel discussion, and to conduct a practical pilot test with the proposed QIs to confirm their applicability in daily clinical practice. We expect the proposed QIs to be used in cardiology training hospitals for creating and refining systems of palliative care for HF patients.

**Methods**

**Selection of Potential QIs and Domains**
The investigators systematically reviewed the existing guidelines and scientific literature to identify potential QIs by searching and referring to PubMed MEDLINE from 2010 through 2016, using search terms “heart failure”, “palliative care”, “quality indicator”, and “guideline”. The investigators also referred to the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care, 3rd edition. Thereafter, the results of the systematic and comprehensive reviews were used to identify best practice for palliative care of HF patients and to develop potential QIs, which were based on the Donabedian structure-process-outcome model. To ensure that there were no omissions in practice measurement, some domains were set for categorization of QIs. The QIs were designed to be performed by general cardiologists, and to be applied to patients who were hospitalized for HF at least twice a year, because 2 or more hospitalizations for HF is considered to be a component of the definition of stage D HF in the Japanese Circulation Society guideline for acute and chronic HF. A clear numerator and denominator were identified for each QI to ensure accurate measurement of the indicator upon application in routine clinical practice.

**Selection of Panel Members**
In reviewing the nomination of expert panel members for assessing potential QIs and developing a final set of QIs, the investigators considered the subspecialties of nominees to ensure that the panel members represented a wide spectrum of palliative care experience. To assemble the multidisciplinary panel members, the investigators attempted to select panel members from various occupations specializing in palliative care for cancer and/or HF. Moreover, the panel members were selected from different institutions, including university hospitals, general hospitals, and other clinical settings to avoid bias. The investigators then contacted the selected nominees to assess their interest and availability for this study.

**Consensus-Building Process: A Modified Delphi Method**
A modified Delphi technique (the RAND Corporation [RAND]/University of California Los Angeles [UCLA] Appropriateness Method) was used to arrive at the final set of QIs. Based on this technique, consensus building was done by panel members in 2 rounds. In the 1st round, the potential QIs were submitted to each panel member, who
was asked to rate each potential QI using a 9-point scale (1, extremely inappropriate; 5, equivocal; 9, extremely appropriate). In the 2nd round, a 1-day face-to-face panel meeting was held in December 2016 in Tokyo, Japan. Panel members anonymously shared their results from the 1st round and discussed each potential QI. When panel members felt the necessity, they proposed minor additions, deletions, or modifications to the set of potential QIs. Any disagreement was resolved through discussion. The panel members rated the revised potential QIs individually, using the same questionnaire and scale from the 1st round. Finally, the QIs with a median score of 7–9 without significant disagreement were included in the final set of QIs for palliative care of HF patients. Disagreement was calculated using a formula that examined the distribution of the ratings according to the RAND/UCLA Appropriateness Method handbook.44

Practical Pilot Test of the Final Set of QIs
After the development of the final set of QIs, a retrospective practical pilot test was conducted to confirm the applicability of the proposed QIs. Consecutive patients who were hospitalized for HF at least twice a year at 3 teaching hospitals (National Cerebral and Cardiovascular Center, Kurume University Hospital, and Tokyo Women's Medical University Hospital) between April 2014 and March 2015 were retrospectively selected. Data were collected from electronic medical records. The performance of the final set of QIs was measured, and percentage scores were obtained for each QI. Institutional review board approval was obtained at our hospital, and the investigation conformed to the principles outlined in the Declaration of Helsinki.

Statistical Analysis
Continuous variables are presented as mean±standard deviation when normally distributed and as median and interquartile range when non-normally distributed. All analyses were performed using JMP version 10 (SAS Institute, Cary, NC, USA).

Table 1. Proposed Set of 35 Quality Indicators for Palliative Care in HF

| Domain / Quality indicator | Numerator | Denominator* | Classification† |
|----------------------------|-----------|--------------|-----------------|
| 1: Structure and process of disease care | | | |
| 1. Presence of multidisciplinary team | Presence of multidisciplinary team that consisted of cardiologist, physicians who completed the palliative care training course, nurse, and pharmacist | Institution | Structure indicator |
| 2. Availability of multidisciplinary team | Preparation of availability of multidisciplinary team in the daytime on weekdays | Institution | Structure indicator |
| 3. Regular discussion by multidisciplinary team | Patients about whom multidisciplinary team discuss at least once a week | HF patients receiving intervention by multidisciplinary team | Process indicator |
| 4. Intervention by multidisciplinary team | Patients receiving intervention by multidisciplinary team | HF patients | Process indicator |
| 2: Appropriate HF treatment and care | | | |
| 5. Consideration of β-blocker prescription | Patients with β-blocker prescription or with a medical record of the reason why β-blocker was not prescribed | HF patients with LVEF <40% | Process indicator |
| 6. Consideration of ACEI/ARB prescription | Patients with ACEI/ARB prescription or with a medical record of the reason why ACEI/ARB was not prescribed | HF patients with LVEF <40% | Process indicator |
| 7. Consideration of MRA prescription | Patients with MRA prescription or with a medical record of the reason why MRA was not prescribed | HF patients with NYHA Class II–IV and LVEF <35% | Process indicator |
| 8. Explanation of ICD therapy | Patients receiving an explanation of the option of ICD therapy | HF patients with NYHA Class II–III, LVEF <35%, and expected prognosis >1 year | Process indicator |
| 9. Explanation of CRT therapy | Patients receiving an explanation of the option of CRT therapy | HF patients with NYHA Class II–IV, LVEF <35%, sinus rhythm, and wide QRS with LBBB morphology | Process indicator |
| 10. Consideration of cardiac transplantation | Patients with history of discussion of candidacy for cardiac transplantation | HF patients under 65 years | Process indicator |
| 11. Evaluation of CAD and valvular heart disease | Patients with evaluation of CAD and valvular heart disease | HF patients | Process indicator |
| 12. Education for secondary prevention | Patients who have been educated in self-care management to prevent rehospitalization for HF | HF patients | Process indicator |
| 13. Consultation service for ICD implantation | Preparation of multidisciplinary consultation service for patients who were candidates for ICD therapy | Institution capable of ICD implantation | Structure indicator |

(Table 1 continued the next page.)
| Domain / Quality indicator                                      | Numerator                                                                 | Denominator*                          | Classification† |
|---------------------------------------------------------------|---------------------------------------------------------------------------|---------------------------------------|-----------------|
| 3: Total pain management                                       | Preparation of in-hospital screening sheet for patient’s total pain, including physical, psychological, social, and spiritual pain | Institution                           | Structure indicator |
| 14. Description of goals of total pain management              | Patients with a medical record of the goals of total pain management       | HF patients receiving intervention by multidisciplinary team | Process indicator |
| 15. Symptom evaluation using quantitative scales               | Patients with evaluation of symptoms using quantitative scales at least once a day | Symptomatic HF patients receiving intervention by multidisciplinary team | Process indicator |
| 16. Management of physical pain                                | Patients with pharmacological and/or non-pharmacological management of physical pain | HF patients with chronic physical pain | Process indicator |
| 17. Preparation of opioid instruction                         | Presence of opioid instruction about efficacy and side effects             | Institution                           | Structure indicator |
| 18. Opioid therapy for patients with refractory dyspnea        | Patients with discussion about opioid prescription                         | HF patients with NYHA Class IV dyspnea refractory to appropriate HF treatment | Process indicator |
| 19. Evaluation of constipation during opioid therapy           | Patients with a medical record of presence or absence of constipation during opioid therapy | HF patients with opioid therapy | Process indicator |
| 20. Evaluation of nausea and vomiting during opioid therapy    | Patients with a medical record of presence or absence of nausea and vomiting during opioid therapy | HF patients with opioid therapy | Process indicator |
| 21. Screening for psychological symptoms                       | Patients with screening for psychological symptoms                         | HF patients                           | Process indicator |
| 22. Availability of psychiatrist                               | Preparation of availability of psychiatrist as required, when psychological symptoms are suspected | Institution                           | Structure indicator |
| 23. Grief care for family members                              | Patients with nursing care plan of grief care for family members before the bereavement | HF patients who died during hospitalization | Process indicator |
| 24. Survey of family structure                                 | Patients with a medical record of key person and family members and the role of family members | HF patients                           | Process indicator |
| 25. Conferencing for discharge support                        | Patients with conference for discharge support before discharge            | HF patients discharged from hospital | Process indicator |
| 26. Consideration of withholding or withdrawing life-prolonging treatment |Patients with a medical record of discussion on withholding and/or withdrawing life-prolonging treatment with the patient or family members | HF patients | Process indicator |
| 27. Multidisciplinary discussion about ICD deactivation at the end of life | Patients with a medical record of multidisciplinary discussion on ICD deactivation | HF patients with ICD who died during hospitalization | Process indicator |
| 28. ICD deactivation prior to death                            | Patients with ICD deactivation prior to death                              | HF patients with ICD who died during hospitalization | Process indicator |
| 29. Multidisciplinary team discussion about palliative sedation | Patients with a medical record of multidisciplinary team discussion before performing palliative sedation | End-stage HF patients with palliative sedation | Process indicator |
| 30. Multidisciplinary team discussion about palliative sedation | Patients with a medical record of informed consent for palliative sedation | End-stage HF patients with palliative sedation | Process indicator |
| 31. Advisory committee for consultation of ethical issues      | Presence of advisory committee for consultation of ethical issues           | Institution                           | Structure indicator |

*Proposed QIs valid for patients with hospitalization for HF at least twice a year. †Classification of indicators was based on the Donabedian model. ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; CAD, coronary artery disease; CRT, cardiac resynchronization therapy; HF, heart failure; ICD, implantable cardioverter defibrillator; LBBB, left bundle branch block; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonist; NYHA, New York Heart Association.
palliative care physicians, 1 general practitioner, 1 psychiatrist, 1 pharmacist, and 2 palliative care nurses. The mean years of experience in palliative care of the panel members was 9±7 years.

Proposed QIs for Palliative Care of HF Patients
After 2 rounds of modified Delphi technique process, a total of 35 QIs comprised the final set for palliative care of HF patients. The proposed QIs were either structure indicators (9/35; 26%) or process indicators (26/35; 74%) based on the Donabedian structure-process-outcome model. No pure outcome indicators were proposed or included. The final set of 35 QIs addressed the following 4 domains: structure and process of disease care (domain 1, 4 indicators), appropriate HF treatment and care (domain 2, 9 indicators), total pain management (domain 3, 18 indicators), and decision support and ethical issue management (domain 4, 4 indicators). The details of the final set of 35 QIs, including descriptions of their numerators and denominators, are presented in Table 1.

Result of Practical Pilot Test of the Proposed QIs
After the development of QIs for palliative care of HF patients, a practical pilot test was conducted to retrospectively measure the proposed QIs. Medical records were retrospectively reviewed, and a total of 131 patients hospitalized for HF at least twice a year between April 2014 and March 2015 in 3 participant hospitals were included. The mean age was 74±15 years, with a male prevalence of 63% (82 patients). Baseline characteristics of the patients are shown in Table 2. There were 10 in-hospital deaths among the 131 patients. The set of the proposed QIs was experimentally measured in these 131 patients and the performance of each QI is summarized in Table 3. Importantly, all of the proposed 35 QIs could be measured retrospectively from medical records. Performance was extremely varied among the QIs, and the following QIs related to process exhibited low performance (<10%): “#4: Intervention by multidisciplinary team”, “#19: Opioid therapy for patients with refractory dyspnea”, and “#22: Screening for psychological symptoms”. The following QIs related to structure also exhibited low performance (0%): “#14: Preparation of screening sheet for total pain”, and “#33: Preparation of medical manual about advance care planning”.

Discussion
In this study, the first set of QIs for palliative care in HF patients was developed. Furthermore, the proposed QIs were preliminarily measured, and we confirmed that all of them could be obtained retrospectively. The study also determined that performance significantly varied among the QIs, and some QIs had low performance.

Current Status of QIs for Palliative Care of HF Patients
The need for palliative care of those living with HF is currently being recognized, but palliative care services are not widely available for this population.15 QIs for palliative care can help with understanding the standard concepts and detailed methods of palliative care and in creating and improving palliative care systems. Unlike palliative care of cancer patients, there are no structured QIs for HF patients. Despite the need for palliative care, actual practice for HF patients has not been strictly defined. Therefore, QIs for palliative care specific to HF patients are strongly warranted. In this study, the first set of QIs for palliative care of HF patients was developed, which could clarify and improve the quality of care. Addressing physical and psychological symptoms and family care by a multidisciplinary team is mandatory for the implementation of palliative care in both cancer and HF patients. Therefore, these elements are included in the QIs of palliative care for cancer patients16,17 and were also included in our proposed QIs for HF patients. Patients with HF continue to receive appropriate and/or aggressive HF treatment to alleviate their symptoms even at the end of life, unlike those with cancer. In addition, invasive/implantable cardiac devices such as implantable cardioverter defibrillator and mechanical circulatory support are sometimes provided to HF patients at the end of life. Thus, these elements, although not included in the QIs of palliative care for cancer

![Table 2. Baseline Characteristics of HF Patients](https://example.com/table2.png)

Data given as mean±SD, median (interquartile range) or n (%). Abbreviations as in Table 1.
A multidisciplinary team approach is relevant and mandatory for palliative care of HF patients, as with cancer patients. This approach is considered to be a fundamental framework for palliative care, and was adopted as one of the domains of the proposed QIs for palliative care in HF patients (domain 1: structure and process of disease care).

Palliative care of HF patients should be provided concurrently with evidence-based HF therapies, because comprehensive HF management can not only prolong survival but also improve symptoms and QoL. Thus, continuous evidence-based HF management is the premise for performing palliative care of HF patients. It is believed that evidence-based HF therapies should be included in the elements of QIs for palliative care of HF patients. Guidelines for the management of HF patients were adopted in our proposed QIs for HF patients.

This study did not directly stand on the initiative of any academic society or project, in contrast to previous reports from Europe and the USA, although experienced and authoritative experts in palliative care for HF were contacted by the investigators, involved in developing the QIs, and had opportunities to express their opinions and views of the present QIs. In the next step, we will cooperate/collaborate with relevant administrative organs and academic societies for the validation, refinement, and promotion of our proposed QIs.

**Four Domains of the Proposed QIs Specific to HF Patients**

European and Japanese guidelines for HF recommend a multidisciplinary team approach as a Class I indication for the management of HF patients. A multidisciplinary team approach is relevant and mandatory for palliative care of HF patients, as with cancer patients. This approach is considered to be a fundamental framework for palliative care, and was adopted as one of the domains of the proposed QIs for palliative care in HF patients (domain 1: structure and process of disease care).

Palliative care of HF patients should be provided concurrently with evidence-based HF therapies, because comprehensive HF management can not only prolong survival but also improve symptoms and QoL. Thus, continuous evidence-based HF management is the premise for performing palliative care of HF patients. It is believed that evidence-based HF therapies should be included in the elements of QIs for palliative care of HF patients. Guidelines

| Table 3. Practical Test for Measuring the Proposed Quality Indicators |
|---------------------------------------------------------------|
| **Domain / Quality indicators**                               | **Total** |
| **1: Structure and process of disease care**                 | **(n=131)** |
| 1. Presence of multidisciplinary team                        | 1/3 (33%) |
| 2. Availability of multidisciplinary team                    | 1/3 (33%) |
| 3. Regular discussion by multidisciplinary team              | 3/11 (27%) |
| 4. Intervention by multidisciplinary team                    | 11/131 (8%) |
| **2: Appropriate HF treatment and care**                     |          |
| 5. Consideration of β-blocker prescription                   | 65/72 (90%) |
| 6. Consideration of ACEI/ARB prescription                    | 58/72 (80%) |
| 7. Consideration of MRA prescription                        | 43/65 (66%) |
| 8. Explanation of ICD therapy                                | 7/26 (27%) |
| 9. Explanation of CRT therapy                               | 3/5 (60%) |
| 10. Consideration of cardiac transplantation                 | 6/26 (23%) |
| 11. Evaluation of CAD and valvular heart disease             | 61/131 (47%) |
| 12. Education for secondary prevention                      | 83/131 (63%) |
| 13. Consultation service for ICD implantation                | 1/3 (33%) |
| **3: Total pain management**                                 |          |
| 14. Preparation of screening sheet for total pain            | 0/3 (0%) |
| 15. Description of goals of total pain management            | 6/11 (55%) |
| 16. Symptom evaluation using quantitative scales             | 2/11 (18%) |
| 17. Management of physical pain                              | 5/8 (63%) |
| 18. Preparation of opioid instruction                        | 1/3 (33%) |
| 19. Opioid therapy for patients with refractory dyspnea     | 0/10 (0%) |
| 20. Evaluation of constipation during opioid therapy         | 2/2 (100%) |
| 21. Evaluation of nausea and vomiting during opioid therapy | 2/2 (100%) |
| 22. Screening for psychological symptoms                     | 8/131 (6%) |
| 23. Availability of psychiatrist                            | 2/3 (67%) |
| 24. Grief care for family members                            | 5/10 (50%) |
| 25. Survey of family structure                               | 131/131 (100%) |
| 26. Conferencing for discharge support                      | 39/121 (32%) |
| 27. Consideration of withholding/withdrawing life-prolonging treatment | 21/131 (16%) |
| 28. Multidisciplinary discussion about ICD deactivation at the end of life | 2/3 (66%) |
| 29. ICD deactivation prior to death                         | 3/3 (100%) |
| 30. Multidisciplinary team discussion about palliative sedation | 1/4 (25%) |
| 31. Informed consent of palliative sedation                  | 3/4 (75%) |
| **4: Decision support and ethical issue management**         |          |
| 32. Preparation of instruction for the illness trajectory of HF | 1/3 (33%) |
| 33. Preparation of medical manual on advance care planning   | 0/3 (0%) |
| 34. Multidisciplinary team discussion about life-prolonging treatment | 2/8 (25%) |
| 35. Advisory committee for consultation of ethical issues    | 1/3 (33%) |

Performance of each quality indicators given as numerator/denominator (%). Abbreviations as in Table 1.
and relevant literature on HF therapies were systematically reviewed and the elements that were thought to be necessary for offering palliative care were adopted as an independent domain (domain 2: appropriate HF treatment and care) of the proposed QIs. In addition to appropriate HF treatment, measuring the patients’ subjective aspects related to their symptoms and QoL is important for HF patients. Although not included in our current proposal, these elements should be considered as QIs of palliative care for HF patients in the future.

In the setting of cardiovascular diseases, medical staff members were unfamiliar with the use of opioid and/or palliative sedation and total pain management, including psychological, social, and spiritual pain, as well as with life-prolonging treatment withholding and/or withdrawal. Therefore, a certain proportion of QIs of total pain management was assigned as an independent domain (domain 3: total pain management). Other characteristics of palliative care of HF included uncertainty about the illness trajectory of HF.21 Decision support was also adopted, including advance care planning as one of the domains of the proposed QIs (domain 4: decision support and ethical issue management). We strongly believe that the proposed QIs cover all the requirements for palliative care of HF patients, secure the quality of care, and promote and spread the concept of palliative care of HF patients.

### Practical Pilot Test of the Proposed QIs in a Clinical Care Setting

In the process of developing the QIs, conducting a practical pilot test before implementation is necessary to determine which QIs will become established components. In our practical pilot test, we experimentally measured our proposed QIs retrospectively from medical charts. Our practical pilot test found that all of the proposed QIs could be obtained retrospectively from medical records and might be applicable in the clinical care settings, despite the lack of data on the effort and time to complete QI measurement. Moreover, the practical pilot test revealed that the performance varied among the QIs. Although generalizability of the results may be limited, the pilot test suggested a need to improve daily practice concerning some indicators in order to perform good-quality palliative care of HF patients. By clarifying the current status of palliative care of HF patients using the proposed QIs, we believe that continuous improvement in the practice of palliative care will occur.

### Results of Measurement of Proposed QIs

Our practical pilot test revealed that the following QIs had low performance: “Intervention by multidisciplinary team”, “Opioid therapy for patients with refractory dyspnea”, and “Screening for psychological symptoms”.

Palliative care is a multidisciplinary means of optimizing QoL and managing symptoms; however, performance of the QI for intervention by multidisciplinary team was low in our practical test. In Western societies, multidisciplinary management has been adopted and debated for decades. In contrast, multidisciplinary team management is just beginning in Japan,22 and our results suggested that more effort should be made to promote a multidisciplinary team approach to the care of HF patients.

Regarding opioid therapy, patients with HF are less likely to be supported by palliative care and opioids than those with cancer,23 as was reflected in our practical test. Thus, opportunities may exist to improve opioid use in symptomatic HF patients using our proposed QIs, although the usefulness of opioids in HF patients with refractory symptoms should be further investigated.

In addition to physical symptoms, many HF patients suffer from psychological symptoms including depression, anxiety and insomnia.24 However, our practical test and previous study reported that routine screening for psychological symptoms was rare, and these symptoms might be under-recognized and under-treated in HF patients.3 Psychological symptoms are associated with worse QoL and increased mortality,25 and we think that screening for these symptoms in HF patients is mandatory as part of palliative care.

### Study Limitations

First, QIs were intended to be extracted from medical records. Performance of the QIs falsely decreased without medical records, even though there were considerations on the elements of the QIs. Serious bias would occur when evaluating the importance of each QIs extracted from medical records, and bias using retrospective data exists. Second, we performed a practical pilot measurement of QIs, but we could not confirm the validity of our proposed QIs in this study. Thus, further studies are needed to validate and generalize our proposed QIs. Third, the practical pilot test included HF patients selected from between 2014 and 2015. The practice of palliative care in HF is evolving year by year, and our results of the performance of QIs may not reflect the current status of practice. Fourth, some HF therapies (i.e., angiotensin-receptor neprilysin-inhibitor or ventricular assist device as a destination therapy) have not been approved in Japan. Thus, generalizability of our proposed QIs might be limited.

### Conclusions

A comprehensive set of 35 QIs for palliative care in HF patients was developed, which is the first set of QIs in this important clinical arena. The practical test was helpful in confirming the measurability of all proposed QIs and suggested that our proposed QIs could clarify and improve the quality of palliative care of HF patients.

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### Disclosures

The authors declare that no conflicts of interest.
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