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The China Patient-centered Evaluative Assessment of Cardiac Events (China PEACE) retrospective heart failure study design

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ABSTRACT

Introduction Heart failure (HF) is a leading cause of hospitalisation in China, which is experiencing a rapid increase in cardiovascular disease prevalence. Yet, little is known about current burden of disease, quality of care and treatment outcomes of HF in China. The objective of this paper is to describe the study methodology, data collection and abstraction, and progress to date of the China Patient-centered Evaluative Assessment of Cardiac Events 5 Retrospective Heart Failure Study (China PEACE 5r-HF).

Methods and analysis The China PEACE 5r-HF Study will examine a nationally representative sample of more than 10 000 patient records hospitalised for HF in 2015 in China. The study is a retrospective cohort study. Patients have been selected using a two-stage sampling design stratified by economic–geographical regions. We will collect patient characteristics, diagnostic testing, treatments and in-hospital outcomes, including death and complications, and charges of hospitalisation. Data quality will be monitored by a central coordinating centre and will address case ascertainment, data abstraction and data management. As of October 2017, we have sampled 15 538 medical records from 189 hospitals, and have received 15 057 (96.9%) of these for data collection, and completed data abstraction and quality control on 7971.

Ethics and dissemination The Central Ethics Committee at the Chinese National Center for Cardiovascular Diseases approved the study. All collaborating hospitals accepted central ethics committee approval with the exception of 15 hospitals, which obtained local approval by internal ethics committees. Findings will be disseminated in future peer-reviewed papers and will serve as a foundation for improving the care for HF in China.

Trial registration number NCT02877914.

Strengths and limitations of this study

- A nationally representative sample of hospitals was generated and the study will generate the largest reported cohort of patients with heart failure in China.
- Medical records were centrally abstracted guided by a standardised data dictionary and governed by rigorous data quality standards.
- Data collected included national disease burden, patient characteristics, pattern of care, in-hospital charges and short-term patient outcomes, which will provide pivotal information for policy makers to improve healthcare quality.
- Data collection is limited to information available in medical records and patient outcomes are limited to those occurring during hospitalisation.

INTRODUCTION

Heart failure (HF) is a significant public health challenge around the world, including in China,[1–4] where cardiovascular disease is the leading cause of death.[5] There were approximately 4.5 million Chinese residents with HF in 2003, and approximately 500 000 incident cases occur every year.[6] Given China's ageing population and increasing prevalence of cardiovascular diseases, the disease burden of HF will rise rapidly in the coming years.[7 8]

Despite the substantially increasing HF burden in China, little is known about patients hospitalised for HF. The most recent data on the national epidemiology of HF in China derives from a survey performed in 2003.[9] While studies from single centres reported the average age of patients with HF has increased and comorbidities have shifted markedly during the past decades,[10–12] national data on demographic characteristics, precipitating factors, comorbidities and echocardiographic characteristics of patients with HF remain unknown. Due to their limited scope, existing studies also report different proportions of HF with preserved ejection fraction and with mildly reduced ejection fraction.[13–15] Further, while it is widely known that use of guideline-directed medication is suboptimal in patients with HF and reduced ejection fraction,[16 17] none of the studies have considered patients' indications in identifying candidates for therapies, and few have considered contraindications to therapy in

calculating treatment rates. Furthermore, comparisons in HF care and its association with outcomes remain unclear across regions in China with different economic conditions and medical resources. Globally, substantial regional variations have been documented in the presentation, underlying causes, management and outcomes of HF,[18–21] but the disparities in HF care between China and other countries have not been fully elucidated due to a lack of standardised definitions for variables in domestic studies which could be used for cross-country comparison. Moreover, validated risk models for Chinese patients with HF do not currently exist and the national economic burden for HF has not been accurately estimated.

To address these knowledge gaps, we use the foundation established by the China PEACE (Patient-centered Evaluative Assessment of Cardiac Events) platform,[22–24] to conduct China PEACE 5 Retrospective Heart Failure Study (China PEACE 5r-HF Study), and generate knowledge from a nationally representative sample of patients hospitalised primarily for HF. The study is descriptive. Rather than testing a specific hypothesis, it seeks to characterise the care and associated patient outcomes of HF, thus providing a foundation for future quality improvement and research. The specific aims of the study are to (1) Estimate the national rate and number of hospital admissions for HF. (2) Describe the demographic and clinical characteristics, echocardiographic findings, patterns of in-hospital care and in-hospital outcomes of patients primarily hospitalised for HF. (3) Examine adherence to guideline recommendations in HF care, including use of evidence-based medicine and devices, and evaluation of left ventricular function. (4) Compare treatment patterns across geographical-economic regions and hospitals, and determine the association between treatment patterns by setting and patient outcomes. (5) Compare differences in patient characteristics, treatment approaches and outcomes between China and other countries. (6) Develop and test prognostic scores to stratify risk. (7) Evaluate national charges of HF in-hospital care.

This paper describes the study methodology, data collection and abstraction, and progress to date of the China PEACE 5r-HF Study. The study findings will identify opportunities for quality improvement and guide the development of strategies and tools to improve outcomes for HF in China.

METHODS

Design overview

The China PEACE 5r-HF Study is a retrospective cohort study that will include a nationally representative sample of more than 10 000 patient hospitalisations for HF from 1 January 2015 to 31 December 2015 in China, to study patient characteristics, treatment patterns and outcomes nationally, and within regions of different socioeconomic development. Candidates for inclusion were those at least 18 years old, with a principal discharge diagnosis of HF, either of new-onset or a decompensation of chronic HF regardless of aetiology. Discharge diagnoses were identified using International Classification of Diseases-Clinical Modification codes 10 (I50.xx, I11.0x, I13.0x or I13.2x), or through discharge diagnosis terms if International Classification of Diseases-10 codes were unavailable.

Sampling design

We used a sampling design similar to that used in the China PEACE-Retrospective Study of acute myocardial infarction (AMI).[22] We generated a nationally representative sample of hospitalisations for HF during 2015 using two-stage random sampling. In the first stage, we identified study hospitals in five strata: eastern-rural, central-rural, western-rural, eastern-urban and central/western-urban regions to reflect diverse setting of economic development and healthcare resources in China. The sampling framework of hospitals consisted of those with the capacity to provide in-hospital care for HF. In each of the rural areas (ie, a county), in-hospital care for HF is mainly provided in the central hospital, which is the largest general hospital with the greatest clinical capacity in the county to treat severe acute illness. In the 287 urban areas, in-hospital care for HF is mainly undertaken by the regionally highest-level hospitals (usually tertiary hospitals), though both secondary and tertiary hospitals have the capacity to provide the care.

We sampled hospitals according to the 2011 hospital list in China, which included 6623 non-military hospitals. In the three rural strata, the sampling framework consisted of the central hospital in each of the predefined rural areas. In the two urban strata, the sampling framework consisted of both the tertiary and secondary hospitals in each of the predefined urban areas, with prison hospitals, specialised hospitals without a cardiovascular division and traditional Chinese medicine hospitals excluded.

In the second stage, we obtained the database of inpatients for HF from each hospital, and identified cases using a systematic random sampling procedure. In each of the five regional strata, we determined the sample size required to achieve 2% precision for describing the primary outcome of in-hospital death, which was estimated from other studies to be 5%.[14 25] To achieve a precision of 2% with an α of 0.05 in each of the two urban strata, assuming an interclass correlation of 0.02 and design effect of 2.6, we would need to sample 2377 medical records among hospitals with an average cluster size of 80. Analogously, to achieve a precision of 2% with an α of 0.05 in each of the three rural strata, assuming an interclass correlation of 0.02 and design effect of 2.2, we would need to sample 2011 medical records among hospitals with an average cluster size of 60. Assuming a participation rate of 85% among selected hospitals, we approached 35 hospitals for participation in each stratum for a total of 175 hospitals (70 urban and 105 rural). We additionally sampled 15 secondary hospitals to each of the urban strata, to ensure that diverse hospitals providing care for HF were included. Consequently, the

total expected sample size was 10 800 patients with HF across 205 hospitals.

Data collection

We trained site investigators to identify all hospitalisations for HF in 2015 from their respective local hospital databases. After we sampled cases at each hospital, we assigned a unique study Identification number (ID) to each case. Site investigators scanned complete hospital medical charts of all sampled patients, with direct identifiers concealed (name, national ID and contact information). All documents of a single patient are collated in one folder with a unique and anonymous participant ID. To facilitate and improve the quality of the scanning process, the coordinating centre developed a software to manage the scan, and provided each study site with a high-speed scanner. All parts of the medical record were required for scanning, including the face sheet, admission note, daily progress notes, procedure notes, medication administration record and diagnostic procedure reports including echocardiograms, laboratory test results, physician orders, nursing notes and discharge summary. Following receipt of each chart, research staff at the coordinating centre checked the hospitalisation ID and date of hospital admission to verify patient identity. The data were evaluated to ensure completeness, quality and concealment of direct identifiers. Incomplete or poorly scanned charts were scanned again. Research staff from the coordinating centre visited 20 sites to assist in processing the sampled cases (figure 1).

We centrally abstracted data from medical records with a standardised data dictionary. As per the China PEACE-Retrospective AMI Study methodology,[22]98% accuracy of medical chart abstraction is ensured by rigorous measures. Two contracted vendors abstracted details of each patient's hospitalisation using their medical charts. One vendor abstracted the part of all medical charts that can be abstracted verbatim without need for interpretation (face sheet, laboratory test results and physician orders) via double entry by separate abstractors to ensure accuracy. The other vendor abstracted the other part of all medical charts (admission record, discharge record, daily record and procedure reports). To ensure accuracy of their interpretation, these latter data are abstracted by certified abstractors and reviewed by senior abstractors. All abstractors received training and were certified. Inner quality control was conducted by vendors. In addition, research staff at the coordinating centre checked the vendors' quality control reports and compared randomly selected records and abstractions for data accuracy.

Data management

All data are protected health information and are securely stored in an encrypted password-protected database at the coordinating centre. Systematic data cleaning includes the identification of potential outliers in the data distribution, and the exclusion of duplicate records by patient and medical record identification numbers. Suspected errors are reviewed and resolved by data managers.

Data elements

To compile a candidate list of potential data elements, we examined relevant literature from both English and Chinese studies. China-specific elements (eg, traditional Chinese medicines) were included whenever appropriate. We supplemented these elements with variables aligned with the American Heart Association Get With The Guidelines-HF (GWTG-HF) quality improvement program[26] and the 2005 ACC/AHA clinical data standards,[27] which will permit international comparisons (table 1). Using these data, we have constructed quality indicators that reflect both clinical eligibility as well as documented contraindications to therapies (table 2).

The Chinese government, which provided financial support for the study in response to a grant application, had no role in the design or conduct of the study; in the collection, management, analysis, and interpretation of the data; or in the preparation or approval of the article.

Patient and public involvement

The China PEACE 5r-HF study is a retrospective study based on abstraction of medical records. Patients were not involved in the recruitment or conduct of the study. The study findings will not be disseminated directly to patients, although the findings will inform quality improvement initiatives in hospitals after the dissemination of the study results. The study does not include patient advisors.

Statistical analyses

We will report summary statistics for patient characteristics, use of diagnostic tests, treatments received and in-hospital outcomes including complications of care across study sites. For each aim, we will use standard parametrical techniques for observational data, including t-tests, χ^2 tests, Wilcoxon rank-sum tests and generalised linear models. Because patient characteristics, treatments and outcomes may be correlated within study sites, analyses will account for the effect of clustering. To examine and adjust for differences between comparison groups, we will use linear, logistic, Cox proportional hazards and Poisson models with a generalised estimating equation approach and hierarchical models to stratify patients according to their risk of adverse outcomes. We will assess the relationship of candidate variables to in-hospital outcomes using appropriate statistical techniques for the dependent variables. We will further refine the list of candidate variables based on their clinical relevance. For those with missing values, we will use statistical methods to impute or discard the variables depending on the percentage of missing values. Alternatively, we may stratify based on the availability of the data.

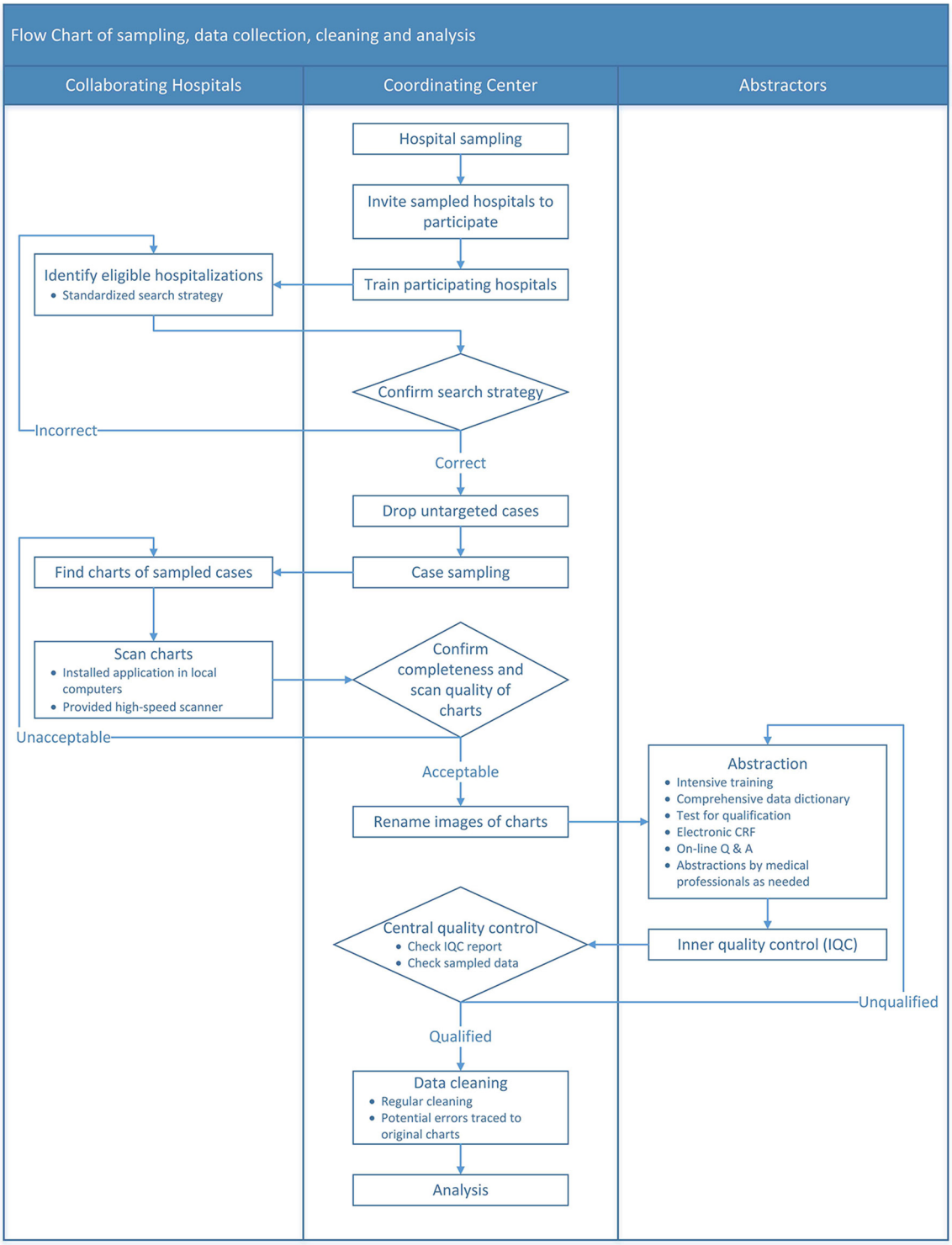

Figure 1 China Patient-centered Evaluative Assessment of Cardiac Events 5 Retrospective Heart Failure Study (PEACE 5r-HF) flow chart and associated quality control assurance strategies. Flow chart should be read from top to bottom. CRF, case report form; Q & A, questions and answers.

Progress to date

Among the sampled 205 hospitals, 11 hospitals did not provide inpatient care for HF or have no admissions for HF in 2015. By the end of October 2017, we obtained lists of patients hospitalised for HF in 2015 from 189 hospitals (figure 2), which included 171 167 hospitalisations. Of these, we sampled 15 538 hospitalisations for the China PEACE 5r-HF Study, and acquired medical records of 15 057 (96.9%). Of the medical records, 14 592 (96.9%) contained all expected sections. For 152 (80%) of the participating hospitals, hospital charges were available to be abstracted from the front page of the medical records. For the remaining 37 hospitals, we asked local investigators to provide hospital charges for sampled admissions

Table 1 China Patient-centered Evaluative Assessment of Cardiac Events 5 Retrospective Heart Failure Study (PEACE 5r-HF) data elements

Category	Example elements
Patient demographics	Age, sex, ethnicity, insurance status and smoking status
Medical history	Myocardial infarction, atrial fibrillation, chronic kidney disease, diabetes mellitus and stroke
Clinical characteristics at admission	NYHA, heart rate, blood pressure, rales and oedema
Comorbidities	Coronary artery disease, cardiomyopathy, hypertension, valvular heart disease, COPD, anaemia and cancer
Precipitating factors	Arrhythmia, ischaemia, respiratory process, pneumonia, uncontrolled hypertension, and non-compliance diet or medicine
Laboratory values	Creatinine, sodium, potassium, haemoglobin, BNP and troponin
Medications prior to admission, and during hospitalisation (including dose)	ACEI/ARB, β-blocker, aldosterone antagonists, diuretics, digoxin, anticoagulants and traditional Chinese medicine
In-hospital procedures	ICD, CRT, pacemaker, PCI and LVAD
Diagnostic procedure results	Echocardiogram (LVEF, size of chambers, pulmonary hypertension, valvular stenosis or regurgitation), chest X-ray and ECG
In-hospital outcomes	Total charge, death, shock, stroke, bleeding, myocardial infarction, length of stay and ICU/CCU duration
Plans at hospital discharge	Medications, diet, weight monitoring and follow-up visit

ACEI, ACE inhibitor; ARB, angiotensin receptor blocker; BNP, brain natriuretic peptide; CCU, cardiac care unit; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronisation therapy; ICD, implantable cardioverter defibrillators; ICU, intensive care unit; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.

Table 2 China Patient-centered Evaluative Assessment of Cardiac Events 5 Retrospective Heart Failure Study (PEACE 5r-HF) performance measures*

In-hospital initiation	Therapies at discharge
ACEI/ARB for HFrEF	ACEI/ARB for HFrEF
β-blockers for HFrEF	β-blockers for HFrEF
Aldosterone antagonist for HFrEF	Aldosterone antagonist for HFrEF
Anticoagulation for atrial fibrillation	Risk intervention
Evaluation of left ventricular systolic function	
CRT therapy in eligible patients	
ICD therapy in eligible patients	

ACEI, ACE inhibitor; ARB, angiotensin receptor blocker; CRT, cardiac resynchronisation therapy; HFrEF, heart failure with reduced ejection fraction; ICD, implantable cardioverter defibrillator.
*Performance measures will be calculated for individuals with clinical indications according to ACC/AHA guidelines and without documented contraindications.

from the financial departments of local hospitals, and 11 of them have completed it.

DISCUSSION

The China PEACE 5r-HF Study is the first study of HF using rigorous sampling design to generate a nationally representative sample of patients and hospitals providing HF care in China. This study will generate the largest report of patients with HF in China and will characterise the national disease burden, patient characteristics, pattern of care, in-hospital charges and short-term patient outcomes, which are all fundamental to public health policy making and care quality improvement. The China PEACE 5r-HF Study is based on the well-established China PEACE research platform, which integrates resources from the Chinese government, a diverse hospital network, and an international research team to translate knowledge of the clinical epidemiology of cardiovascular disease into action for the benefit of patients. The China PEACE 5r-HF Study will also take the advantage of the China PEACE platform significantly elevating the data quality with techniques regularly employed by international clinical trials such as integrated central and on-site monitoring as well as source document verification. This

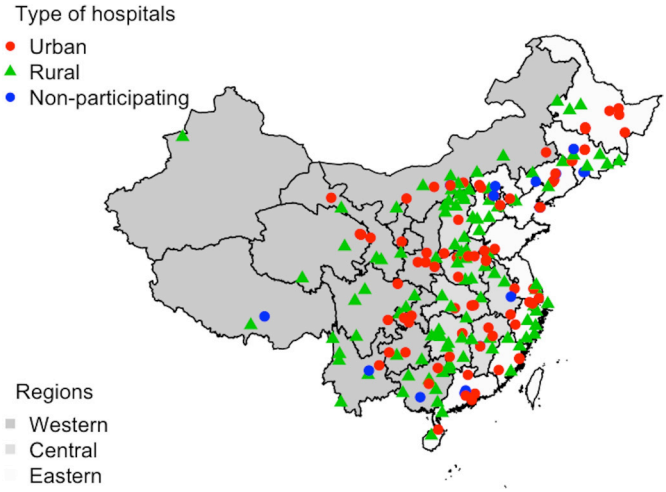

Figure 2 Geographical distribution of participating hospitals in the China Patient-centered Evaluative Assessment of Cardiac Events 5 Retrospective Heart Failure Study (PEACE 5r-HF). Of the 205 sampled hospitals, 16 were unable or unwilling to participate and 189 provided cases for the China PEACE 5r-HF Study.

project also elicits the active participation of hospitals across China to ensure that study results are disseminated broadly for the purpose of quality improvement.

The China PEACE 5r-HF Study will characterise the current HF burden in China, supporting national estimates of annual hospitalisations for the first time. HF hospitalisations bring a significant strain on healthcare systems and national health expenditures all around the world. The resources dedicated to the hospital care of HF hospitalisation in China remain unclear. This study will have the capacity to estimate charges at the national, regional, hospital and patient levels. These results will inform resource allocation to achieve an economical equity and efficiency balance.

This study will generate evidence to inform contemporary HF medical practice and improve outcomes. Investigating quality measures for HF care may reveal gaps between current clinical guidelines and practice in the real world, therefore highlighting the need for future quality improvement efforts to ensure that all patients receive appropriate treatment. We anticipate substantial regional and hospital variation in a broad range of institutions. These findings will indicate opportunities for improvement that are concentrated in some regions, hospitals and patient groups, and identify opportunities to enhance access to medical resource and equity, and improve the quality and value of care. Geographical variations in clinical characteristics and care of patients hospitalised with HF between China and other countries will have important implications for global clinical trials and outcome studies in HF. Risk models derived and validated in domestic patients with HF will help clinicians guide care and researchers conduct observational studies in the future. All these findings may influence policy pertinent to HF care in China, as well as offer important lessons for other low-income and middle-income countries.

The China PEACE 5r-HF Study has some notable strengths in its design. It contains the largest and the only representative sample of hospitalisations for HF in China and therefore includes patients from diverse geographical regions and institutions with widely varied capacities. Information will be available on topics that have not been well studied (eg, the use of implantable cardioverter defibrillator or cardiac resynchronisation therapy in patients with HF). International comparisons will also be possible given the alignment of key data elements with the GWTG-HF and 2005 ACC/AHA clinical data standards. Finally, further targeted examination of additional data elements not included in the initial case report forms can be performed as novel questions arise, as the Chinese National Center for Cardiovascular Diseases will maintain a physical copy of all charts after the initial abstraction.

This study is further distinguished by its use of data quality control strategies, which are much more common in multinational clinical trials than in large retrospective studies. We devoted significant attention to data quality at the stages of case ascertainment, data abstraction and data management. For example, research staff rigorously monitored study sites to identify all hospitalisations for HF from census databases. Staff also ensured that medical records for sampled cases were physically found, properly copied and transmitted in full whenever possible. In addition, this study provided central training for abstractors and required rigorous standards for both initial certification and recertification. Medical records from abstractors who did not meet recertification requirements were reabstracted by a second reviewer.

The China PEACE 5r-HF Study has some limitations. First, study findings are dependent on the accuracy and completeness of abstracted medical charts. A common problem caused by this issue is underestimation of comorbidities or complications due to missed documentation. However, the record of lab tests, image examinations, medications and procedures are very reliable because these records are subjective and linked with administrative activities, such as fee charge. Moreover, poor documentation of key variables will be an important target for quality improvement. Second, HF diagnoses were based on medical charts and were made by local clinicians, potentially resulting in misclassifications, because HF remains a challenging clinical diagnosis. However, the principal discharge diagnosis of HF has a high positive predictive value compared with other case assessment strategies. Finally, our study is also restricted to measuring in-hospital outcomes, as we are unable to link patient-level data to a national registry of death. However, the long lengths of stay in Chinese hospitals relative to those in Western countries should permit more robust estimates of short-term complications including death.[14 28 29] Moreover, long-term outcomes and patient experiences will be collected in the recently launched China PEACE 5p-HF Study.

The China PEACE 5r-HF Study is the first study on a nationally representative sample of Chinese patients with HF that assesses the characteristics, in-hospital care and outcomes across patients, hospitals and regions in China. It provides a platform through which government, healthcare providers, and research organisations can translate knowledge of the clinical epidemiology of HF into improved care for patients in the context of increasing burden.

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Contributors HMK and JL designed the study and take responsibility for all aspects of it. YY wrote the first draft of the article, with further contributions from XL, YL, FAM, HMK and JL. ZZ performed statistical analysis. All authors approved the final version of the article.

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Competing interests HMK works under contract with the Centers for Medicare & Medicaid Services to develop and maintain performance measures, is chair of a cardiac scientific advisory board for United Health, and is the recipient of research grants from Medtronic, Inc and Johnson & Johnson through Yale University.

Patient consent Not required.

Ethics approval The Central Ethics Committee at the Chinese National Center for Cardiovascular Diseases approved the study. All collaborating hospitals accepted central ethics approval with the exception of 15 hospitals, which obtained local approval by internal ethics committees. Trial Registration Number: NCT02877914.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement This is a protocol manuscript, so there are no additional unpublished data.

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