China Patient-centered Evaluative Assessment of Cardiac Events Prospective Study of Acute Myocardial Infarction: Study Design

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Abstract

Background: Despite the rapid growth in the incidence of acute myocardial infarction (AMI) in China, there is limited information about patients' experiences after AMI hospitalization, especially on long-term adverse events and patient-reported outcomes (PROs).
Methods: The China Patient-centered Evaluative Assessment of Cardiac Events (PEACE)-Prospective AMI Study will enroll 4000 consecutive AMI patients from 53 diverse hospitals across China and follow them longitudinally for 12 months to document their treatment, recovery, and outcomes. Details of patients' medical history, treatment, and in-hospital outcomes are abstracted from medical charts. Comprehensive baseline interviews are being conducted to characterize patient demographics, risk factors, presentation, and healthcare utilization. As part of these interviews, validated instruments are administered to measure PROs, including quality of life, symptoms, mood, cognition, and sexual activity. Follow-up interviews, measuring PROs, medication adherence, risk factor control, and collecting hospitalization events are conducted at 1, 6, and 12 months after discharge. Supporting documents for potential outcomes are collected for adjudication by clinicians at the National Coordinating Center. Blood and urine samples are also obtained at baseline, 1- and 12-month follow-up. In addition, we are conducting a survey of participating hospitals to characterize their organizational characteristics.
Conclusion: The China PEACE-Prospective AMI study will be uniquely positioned to generate new information regarding patient's experiences and outcomes after AMI in China and serve as a foundation for quality improvement activities.

Key words: Acute Myocardial Infarction; Outcomes Research; Patient-reported Outcome Measures; Prospective Cohort

Introduction

Understanding major adverse events and patient-reported outcomes (PROs) after acute myocardial infarction (AMI) is fundamental to improving the quality and effectiveness of health care.[1] With the emergence of validated instruments to measure health status, physical function, and other PROs, several observational studies in Western countries have explored

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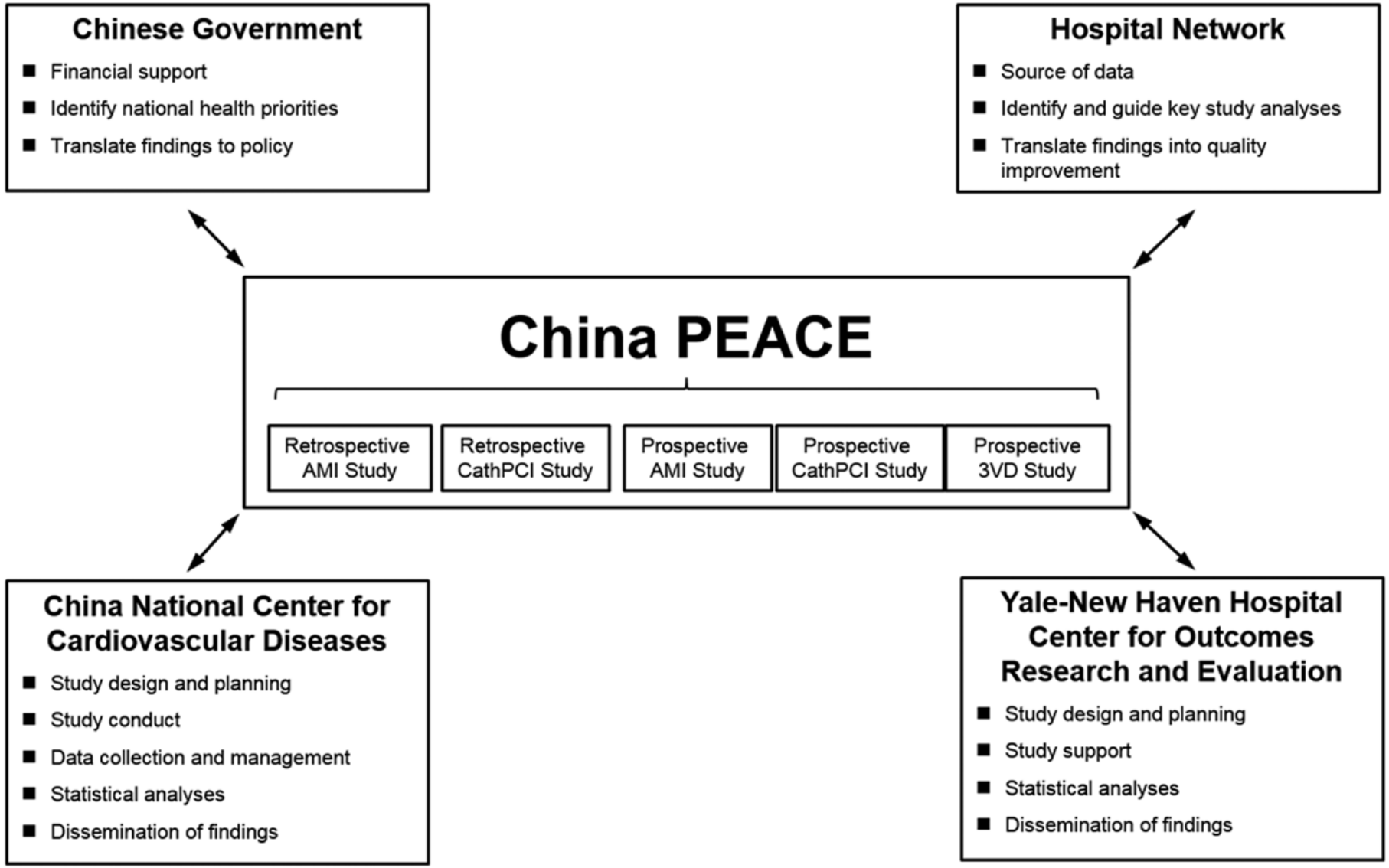

Figure 1: The China Patient-centered Evaluative Assessment of Cardiac Events Initiative. Key partners include the Chinese government, collaborating hospitals, the China National Center for Cardiovascular Disease, and the Yale-New Haven Hospital, Center for Outcomes Research and Evaluation. AMI: Acute myocardial infarction; PCI: Percutaneous coronary intervention; 3VD: Revascularization in patients with triple-vessel disease.

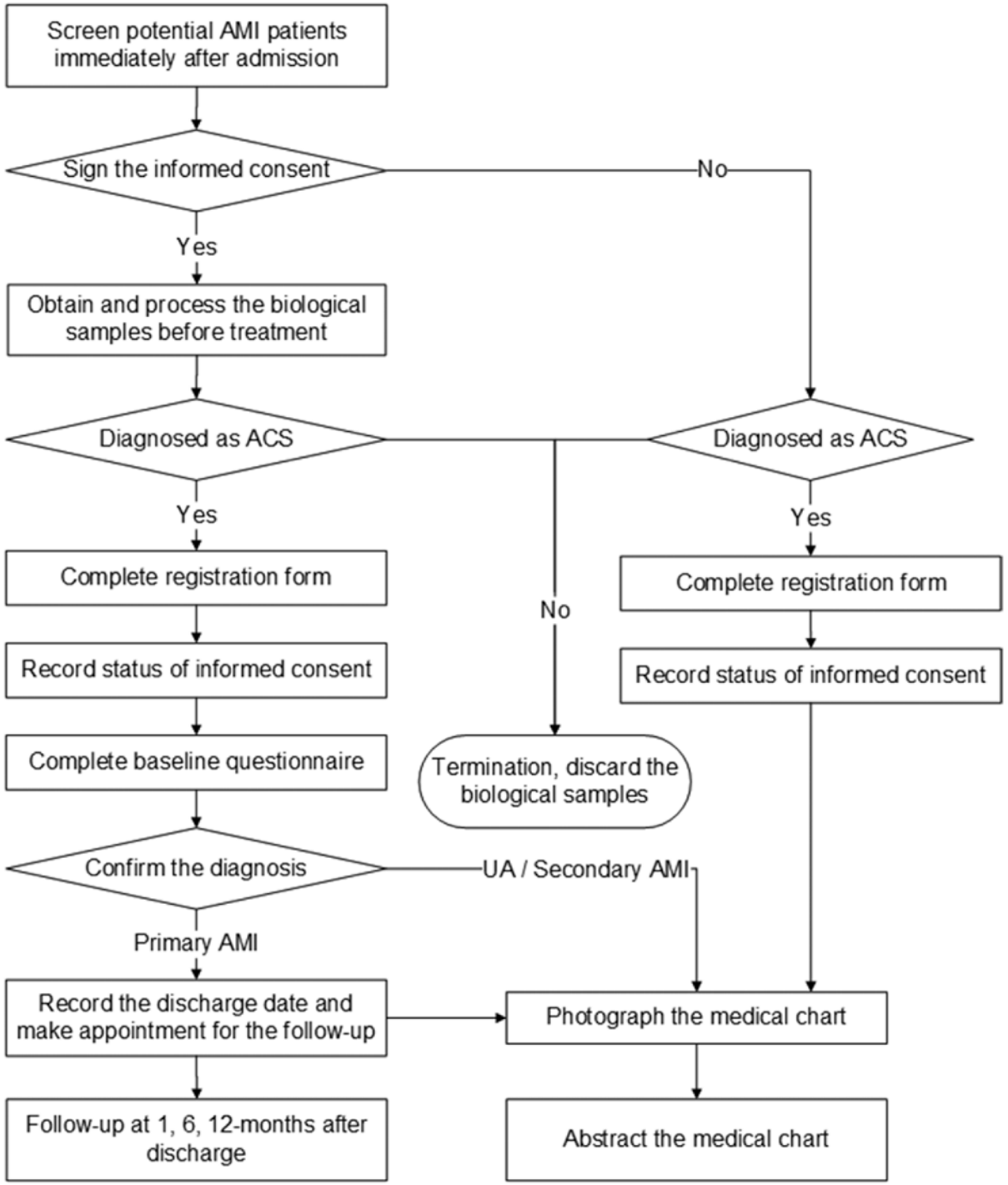

Figure 2: The China Patient-centered Evaluative Assessment of Cardiac Events Prospective Study of Acute Myocardial Infarction study flow chart. AMI: Acute myocardial infarction; ACS: Acute coronary syndrome; UA: Unstable angina.

Table 1: Data collected during the AMI index hospitalization and follow-up

Domain		Assessment			
	Scale	Baseline	1-month	6-month	12-month
Medical charts abstraction		√			
Medical history/risk factors		√			
Clinical characteristics		√			
Pre-AMI care		√			
Diagnostic tests		√			
Treatments/procedures		√			
Discharge medications		√			
In-hospital outcomes		√			
Patient interviews					
CVD functional status	SAQ[14]	√	√	√	√
Health-related quality of life	EQ-5D[15]	√	√	√	√
Depression	PHQ-8[16]	√	√	√	√
Stress	PSS[17]	√	√	√	√
Social support	ESSI[18]	√			√
Obstructive sleep apnea	MBQ[19]	√			
Cognitive function*	MMSE[20]	√		√	√
Sexual activity*	Lindau[21]	√	√		√
Major vascular events		√	√	√	√
Any hospitalization		√	√	√	√
Onset of symptoms					
Seeking care for symptoms		√			
Health care service		√			√
TCM clinic/therapies		√			√
Health care insurance		√			√
Medical expenses		√			√
Socioeconomic status		√			√
Education		√			
Work status		√			√
Marital/living status		√			√
Household income		√			√
Health knowledge		√			

Table 1: Continued

Domain	Assessment				
	Scale	Baseline	1-month	6-month	12-month
Risk factors					
Blood pressure		√	√	√	√
Family history		√			
Smoking status		√			
Lifestyle factors		√			√
Physical activity		√			
Alcohol consumption		√			
Preventive medications			√	√	√
BMI/hip circumference		√	√	√	√
Local lab tests					
Blood cell count			√		√
Urine analysis			√		√
Alanine transaminase		√	√		√
Creatinine/BUN		√	√		√
Blood glucose			√		√
Electrocardiogram			√	√	√
Central lab analysis					
Blood lipid profile		√			√
HbA1c		√			√
hs-CRP		√			√
Bio-samples for long-term storage					
Plasma/serum		√	√†		√
DNA		√			
RNA from periphery blood		√			√
Urine		√	√†		√

*Only performed in 6 hospitals (3 tertiary and 3 secondary hospitals, from 3 provinces); †Only collected in secondary hospitals. AMI: Acute myocardial infarction; CVD: Cardiovascular disease; SAQ: Seattle angina questionnaire; EQ-5D: EuroQol group 5-dimension self-report questionnaire; PHQ-8: Patient health questionnaire 8-item depression scale; PSS: Perceived stress scale; ESSI: Enhancing recovery in coronary heart disease (ENRICHD) social support inventory; MBQ: Modified Berlin questionnaire; MMSE: Mini mental state examination; TCM: Traditional Chinese medicine; BUN: Blood urea nitrogen; HbA1c: Hemoglobin A1c; hs-CRP: High-sensitivity C-reactive protein; DNA: Deoxyribonucleic acid; RNA: Ribonucleic acid; BMI: Body mass index.

Conclusion

- The China PEACE-Prospective AMI study is uniquely positioned to help improve the quality of care and patient outcomes for China and similar LMICs by generating novel, high-quality, and comprehensive data about patients' experience following hospitalizations for AMI.
- The partnership among the Chinese government, an expert clinical trial group, a large network of hospitals with geographic and capability diversity, and international experts in outcomes research, will be leveraged to create a platform for research on cardiovascular diseases which will facilitate policy-making and inform the development of novel quality improvement tools.