Heart failure requiring urgent therapy represents a burgeoning health care burden. Although acute heart failure syndromes are commonly defined as a change in chronic heart failure signs and symptoms requiring urgent therapy, the presentation, development, and response to treatment is highly dependent on individual patient characteristics. This heterogeneity has led to challenges in interpreting widely differing study methods, including eligibility requirements and outcome measures. To improve interpretation of results and translate such information to better patient care, it is essential to present an accurate description of the patient population and study design. Based on existing recommendations and expert consensus, the authors present standardized reporting criteria to improve interpretability of research in this challenging cohort. (J Am Coll Cardiol 2012;60:822–32) © 2012 by the American College of Cardiology Foundation
The emergent evaluation and management of patients with possible acute heart failure syndromes (AHFS) remains a significant challenge. Unlike major advances in the assessment and treatment of patients with acute coronary syndromes, the diagnostic tools and therapeutic options for patients presenting with AHFS have changed little for decades (1), and the complexity of AHFS has led to a practice of risk aversion and extremely high hospitalization rates (2–5). These difficulties, as well as the increasing prevalence of heart failure, have placed an enormous burden on health care resources worldwide (2).

The cohort of AHFS patients is diverse. Although they might be commonly defined as patients with a gradual or rapid change in chronic heart failure signs and symptoms resulting in a need for urgent or unscheduled therapy (4,6,7), the development, presentation, and response to treatment is dependent on each individual’s pathophysiology and comorbidities. Researchers have studied a wide range of patient populations with different eligibility criteria and medical histories and using divergent outcome measures. To better interpret available research in the light of this study-related heterogeneity and to improve the level of evidence supporting the acute evaluation and management of the AHFS patient, it is critical to present a thorough description of the patient population evaluated. Methods of patient selection, demographics and medical history of eligible patients, intervention or evaluation protocols, outcome measures, and time intervals for measurements must be consistently reported. Based on existing recommendations and expert consensus, these guidelines aim to provide investigators a framework for reporting studies of patients with possible AHFS. By providing these standardized reporting criteria, we hope to improve the interpretability of research in this challenging patient cohort and thus to improve patient care through better application of evidence-based medicine.

**Development of Criteria**

A working group of the Emergency Management and Research Group in Acute Heart Failure met in May 2007 to begin developing the reporting guidelines. Eight areas of importance were identified and assigned to working group members to develop initial recommendations based on existing guidelines:

1. Screening and recruitment
2. Demographics
3. Previous cardiac diagnosis, risk factors, medical history
4. Acute presentation (clinical characteristics)
5. Test reporting and observation care
6. Patient course including response to treatment
7. Outcomes
8. Follow-up period

The initial recommendations were modified and circulated to working group members before in-person meetings in October 2007, May 2008, October 2008, and May 2009. At these meetings, each proposed reporting element was discussed for incorporation as a core measure, supplemental measure, or dropped from further consideration.

The working draft was then distributed among the various stakeholders, including other members of Emergency Management and Research Group in Acute Heart Failure, for expansion and revision throughout 2010 and early 2011. Representatives of the Society of Academic Emergency Medicine, the American College of Emergency Physicians, the American Heart Association, the American College of Cardiology, the Heart Failure Society of America, the Society of Chest Pain Centers, and the Working Group of Acute Cardiac Care of the European Society of Cardiology were given the opportunity to review and revise the reporting guidelines. Once consensus was achieved, the
Standardized Reporting Guidelines for Studies Evaluating Suspected Acute Heart Failure Syndromes in the Emergency Department were finalized for publication. The guidelines have been endorsed by Society of Academic Emergency Medicine, American College of Emergency Physicians, American Heart Association, Society of Chest Pain Centers, and the Working Group on Acute Cardiac Care of the European Society of Cardiology.

Structure and Suggestions for Use of This Document

These guidelines emphasize the minimum information that should be reported and additional information that would be of benefit to report when presenting studies of the evaluation and management of AHFS. The structure is similar to recently introduced reporting guidelines for possible acute coronary syndromes (8). Where available, we have used the definition of data elements as provided by the American College of Cardiology, American Heart Association, European Society of Cardiology, Heart Failure Society of America, Society of Chest Pain Centers, or World Heart Federation (9–18). Where definitions do not exist or are insufficient to clarify ambiguity in reporting, new definitions have been provided.

Throughout the document, bolded items are identified as core components (Table 1), and these should be reported in all studies of the evaluation and management of AHFS. Supplemental items are not bolded but should be reported whenever possible. Core components represent the minimal amount of information necessary to compare and contrast studies and can be used by investigators to guide data collection and presentation of results. As well as facilitating the design of studies, peer reviewers evaluating manuscripts for publication may use these criteria to determine whether sufficient information is reported to allow readers to place the study in appropriate context and compare results with those of other publications. Clinicians may find it helpful to use the core criteria to determine whether reported populations are similar to the patients they treat and thus facilitate an evidence-based medicine approach to the acute evaluation and management of AHFS. Reporting AHFS studies in accordance with the guidelines will facilitate systematic review and meta-analysis, maximizing the impact of research on clinical practice.

1. Screening and Recruitment

Patients with AHFS are a heterogeneous population. The performance of diagnostic and prognostic interventions is dependent on the severity, prevalence, and pathophysiology of the disease in the study population, as well as comorbid conditions or alternative diagnoses. The methods of screening and recruiting subjects and study inclusion and exclusion criteria are key factors affecting these parameters and thus should be reported.

1.1. Specific ages for inclusion and exclusion

1.2. Procedure for identifying population to be screened

1.2.1. Signs, symptoms, or other criteria to prompt screening

1.2.2. Days and times of screening

1.2.3. Location of screening

1.3. Method of screening

1.3.1. By symptoms at presentation

1.3.1.1. The specific symptoms used for inclusion and exclusion

1.3.1.2. The time of onset and duration of symptoms used for inclusion and exclusion

1.3.2. By emergency department (ED) discharge/hospital admission diagnosis

1.3.3. By hospital discharge diagnosis

1.3.4. By diagnostic testing

1.3.4.1. Use of diagnostic testing (e.g., ordering echocardiography)

1.3.4.2. Results of diagnostic testing (e.g., elevated B-type natriuretic peptide [BNP])

1.3.5. By administration of medications (e.g., nitroglycerin, furosemide)

1.3.6. By pre-specified criteria (e.g., Framingham Criteria)

1.4. Account for patients screened and included and excluded from the study

1.4.1. Flow diagram to account for all patients

1.4.2. Report total ED census for participating institution(s)

1.4.3. Report ED volume of potential patients (e.g., total number of patients evaluated for AHFS)

1.4.4. Report volume of potential patients screened

2. Demographics

A description of the patients studied is important to understand the relevance of the study to specific populations to allow comparisons of different patient populations and for risk adjustments.

2.1. Sex

2.2. Age

2.3. Race, including method of determination (19):

2.3.1. American Indian or Alaska Native

2.3.2. Asian

2.3.3. Black or African American

2.3.4. African descendent

2.3.5. Native Hawaiian or other Pacific Islander

2.3.6. White

2.3.7. Other

2.3.8. Mixed race

2.4. Ethnicity

2.4.1 Hispanic

2.4.2. Non-Hispanic

2.5. Insurance status (refers to the primary payor)

2.5.1. Private refers to all private medical insurance.
2.5.2. Self-pay refers to no identifiable source of payment for medical bills.
2.5.3. Other refers to local, regional, or national government insurance program, charity, tax levy, or other source of payment
2.5.4. In the United States, differentiate Medicare from Medicaid

2.6. Mode of transport (means by which the patient arrived at the ED)
2.6.1. Self/family
2.6.2. Ground ambulance (basic, intermediate, or advanced)
2.6.3. Air ambulance
2.6.4. Other

2.7. Source of patients (place where patient resides at time of acute presentation)
2.7.1. Home
2.7.2. Other hospital facility
2.7.3. Extended care facility
2.7.4. Jail or prison
2.7.5. Other

3. Previous cardiac diagnosis, risk factors, and medical history
In the acute care setting, physicians frequently do not have access to detailed medical records and, therefore, must typically rely on patient self-report. In studies of AHFS conducted in the acute care setting, it is acceptable to rely on patient self-report of cardiac risk factors. However, the investigators must report the method of evaluation.

3.1. Hypertension
3.2. Family history of early coronary artery disease (CAD) (acute myocardial infarction [MI], angina, or sudden cardiac death in a first-degree relative, male younger than 55 years of age, female younger than 65 years of age)

3.3. Diabetes mellitus (regardless of duration of disease or use of specific medications)
3.3.1. Type of diabetes mellitus treatment (diet, oral agents, insulin alone, or insulin with oral agents)
3.3.2. Year of onset or first diagnosis

3.4. Smoking
3.4.1. Current (within 1 month)
3.4.2. Recent (stopped between 1 month and 1 year before enrollment)
3.4.3. Former (stopped >1 year before enrollment)
3.4.4. Never smoker

3.5. Hypercholesterolemia or hyperlipidemia
3.6. Drug and alcohol use
3.6.1. Amount and duration
3.6.2. Results of toxicology testing
3.6.3. Current (within 1 month)
3.6.4. Recent (stopped between 1 month and 1 year before enrollment)
3.6.5. Former (stopped >1 year before enrollment)

3.7. Renal Insufficiency
3.7.1. Elevated creatinine
3.7.2. Reduced creatinine clearance or glomerular filtration rate (GFR); investigators must identify the method used to calculate these variables
3.7.3. Albuminuria

3.8. Presence of obesity
3.8.1. Body mass index

3.9. AMI. If the previous AMI is confirmed through medical record review and meets the European Society of Cardiology/American College of Cardiology/American Heart Association/World Heart Federation criteria (16), this should be noted. If the history of AMI cannot be confirmed to meet these criteria, then it should be recorded as “reported history of AMI.” If an alternative definition is used, this should be given.

3.10. Known cardiovascular disease
3.10.1. Heart failure (any previous episodes). If the presence of heart failure is documented in the medical record, this should be noted. Otherwise, it should be reported as “self-reported history of heart failure.”
3.10.1.1. Etiology of heart failure (if known)
3.10.1.2. Preserved or reduced systolic function and definition used

3.10.2. CAD. If the presence of CAD is documented in the medical record through objective criteria such as cardiac catheterization with significant stenosis, demonstrated electrocardiographic changes, perfusion defects, or wall motion abnormalities on exercise or pharmacological imaging studies, this should be noted (11). Otherwise, it should be recorded as “self-reported history of CAD.”
3.10.2.1. Revascularization (percutaneous coronary intervention, coronary artery bypass graft)
3.10.2.1.1. Type, number of grafts or stented vessels, year

3.10.3. Ventricular arrhythmias
3.10.3.1. Ventricular tachycardia resulting in symptoms or acute intervention
3.10.3.2. Ventricular fibrillation
3.10.4. Cardiac arrest
3.10.5. Atrial arrhythmias
3.10.5.1. Atrial fibrillation or flutter (20)
3.10.5.1.1. First detected
3.10.5.1.2. Paroxysmal
3.10.5.1.3. Persistent

3.10.6. Peripheral vascular disease
3.10.6.1. Peripheral arterial disease
3.10.6.2. Venous thromboembolic disease

3.10.7. Cerebrovascular events
3.10.8. Automatic internal cardiac defibrillator (ICD)
3.10.8.1. ICD only
3.10.8.2. Cardiac resynchronization therapy defibrillator (cardiac resynchronization therapy + ICD)

3.10.9. Pacemaker
3.10.9.1. Single chamber, dual chamber
3.10.9.2. Biventricular

3.10.10. Valvular disease
3.10.10.1. Native valve
3.10.10.2. Prosthetic valve

3.11. Previous objective assessments of cardiac function
3.11.1. Previous ejection fraction
3.11.1.1. Time interval from testing to ED visit
3.11.1.2. Method used to assess ejection fraction (e.g., echocardiography, catheterization, nuclear study)

3.11.2. Most recent known ejection fraction
3.11.3. Presence or absence of diastolic dysfunction, ventricular hypertrophy, regional wall motion abnormalities, valvular disease

3.11.4. Baseline (well or dry weight) BNP or N-terminal pro–BNP (NT-proBNP) values

3.12. Pulmonary disease
3.12.1. Asthma
3.12.2. Chronic obstructive pulmonary disease
3.12.3. Other

3.13. Home treatment
3.13.1. Current medications and definition used for current
3.13.1.1. Diuretics
3.13.1.2. Vasodilators (e.g., nitroglycerin, hydralazine)
3.13.1.3. Angiotensin–converting enzyme inhibitors
3.13.1.4. Angiotensin-receptor blockers
3.13.1.5. Inotropes
3.13.1.6. Aspirin
3.13.1.7. Adenosine diphosphate receptor inhibitors
3.13.1.8. Beta-blockers
3.13.1.9. Calcium channel blockers
3.13.1.10. Oral anticoagulants
3.13.1.10.1. Coumadin
3.13.1.10.2. Others
3.13.1.11. Aldosterone antagonists
3.13.1.12. Digoxin
3.13.1.13. Alpha antagonists
3.13.2. Contraindications to recommended treatments
3.13.3. Other home treatments

4. Acute presentation
The vast majority of patients with AHFS will have dyspnea as their chief symptom. A clear yet concise description of the degree and magnitude of breathlessness is therefore requisite for any investigation of AHFS, particularly those that involve stratification by severity of presentation or cross-population comparison. Quantification of symptom severity using tools such as the New York Heart Association classification system or relative Likert scales (21,22) is considered useful, but their validity may be limited by the subjectivity inherent to patient self-assessment. The recently proposed axis model should be taken into consideration, however its utility remains to be determined (23).

4.1. Dyspnea
4.1.1. Onset
4.1.1.1. Abrupt
4.1.1.2. Gradual

4.1.2. Character
4.1.2.1. Exertional only (mild)
4.1.2.2. At rest (moderate)

4.1.2.2.1. Without orthopnea
4.1.2.2.2. With orthopnea
4.1.2.2.3. Paroxysmal nocturnal

4.1.2.3. Respiratory distress (severe)
4.1.2.3.1. Needs immediate noninvasive ventilatory support

4.1.2.4. Respiratory failure
4.1.2.4.1. Needs immediate intubation

4.1.3. Comparison with baseline

4.1.4. Respiratory rate

4.1.5. Oxygen saturation
4.1.5.1. Indicate amount of supplemental oxygen currently administered

4.1.6. Signs of pulmonary congestion
4.1.6.1. Rales
4.1.6.1.1. Basilar only
4.1.6.1.2. Less than one-half lung field
4.1.6.1.3. More than one-half lung field

4.1.6.2. Wheeze
4.1.6.3. Accessory muscle use

4.2. Other signs and symptoms
4.2.1. Murmur (location, timing, and intensity)
4.2.2. Gallop (S3, S4)
4.2.2.1. Auscultation
4.2.2.2. Phonocardiography

4.2.3. Elevated jugular venous pressure
4.2.4. Peripheral edema
4.2.5. Hepatic congestion
4.2.6. Ascites
4.2.7. Anasarca
4.2.8. Weight at baseline
4.2.9. Weight gain
4.2.10. Height (for determination of GFR)
4.2.11. Fatigue
4.2.12. Syncope
4.2.13. Chest pain
4.2.14. Palpitations

4.3. Hemodynamic status. Hemodynamic status on presentation is a critical determinant of AHFS
management (24, 25) and has significant implications for clinical trial design. Uniform reporting of relevant parameters, therefore, is essential. Blood pressure is a particularly important variable to include and should be presented as needed to best characterize patient cohorts (7, 26).

4.3. Blood pressure
4.3.1. Continuous integers
4.3.1.1. Systolic
4.3.1.2. Diastolic
4.3.1.3. Categorical (report cutoffs used)
4.3.1.4. Hypertensive
4.3.1.5. Normotensive
4.3.1.6. Hypotensive
4.3.1.7. Cardiogenic shock (hypotension with signs of hypoperfusion)

4.3.2. Heart rate
4.3.3. Other parameters (report if available along with method [invasive or noninvasive] by which they were obtained)
4.3.3.1. Cardiac index/output
4.3.3.2. Systemic vascular resistance
4.3.3.3. Stroke volume
4.3.3.4. Pulmonary capillary wedge pressure

4.4. Precipitating factors. These are the factors that are considered causative for the acute event rather than contributory to the underlying etiology of heart failure.
4.4.1. Uncontrolled hypertension
4.4.2. Acute cardiac ischemia/infarct
4.4.3. Arrhythmia
4.4.4. Noncompliance (e.g., medication, diet)
4.4.5. Toxicity (e.g., cocaine, amphetamines)
4.4.6. Acute valve problems (e.g., acute mitral regurgitation)
4.4.7. Myocarditis
4.4.8. High-output states (e.g., thiamine deficiency, thyrotoxicosis, sepsis, Paget’s disease, severe anemia)
4.4.9. Systemic infections (e.g., pneumonia, urinary tract)
4.4.10. Pulmonary embolism
4.4.11. Development of comorbid states (e.g., renal failure, anemia, hypothyroidism)

5. Test Reporting
The tests used to evaluate patients with AHFS in the acute setting typically include the electrocardiogram (ECG), chest radiographs, and laboratory assays. Each of these should be reported with sufficient detail to enable accurate interpretation of the results. The lab result section (5.3) is meant to be an overview for both diagnostic and therapeutic studies. More detailed recommendations about biomarker reporting are available elsewhere (27–30).

5.1. ECG
5.1.1. Person(s) interpreting the ECGs
5.1.2. Timing of ECG relative to presentation
5.1.2.1. Presenting ECG
5.1.2.2. Out-of-hospital ECG
5.1.2.3. Serial in-hospital ECGs
5.1.3. Findings suggestive of acute coronary syndrome
5.1.3.1. Rate
5.1.3.2. Rhythm
5.1.3.3. Overall categorization of the ECG (31)
5.1.3.3.1. Normal
5.1.3.3.2. Nonspecific ST-T wave changes
5.1.3.3.3. Abnormal but not diagnostic of ischemia
5.1.3.3.4. Infarction or ischemia known to be old
5.1.3.3.5. Ischemia or infarction not known to be old
5.1.3.3.6. Consistent with AMI (ST-segment elevation or new left bundle branch block)
5.1.4. Dynamic ECG analysis
5.1.5. Presence of left bundle branch block

5.2. Chest radiograph
5.2.1. Procedure used for imaging
5.2.1.1. Anteroposterior (portable) technique
5.2.1.2. Posteroanterior and lateral technique
5.2.2. Person(s) interpreting the chest radiograph
5.2.3. Findings on the chest radiograph
5.2.3.1. Cardiomegaly
5.2.3.2. Pulmonary vascular redistribution
5.2.3.2.1. Mild
5.2.3.2.2. Moderate (e.g., Kerley B lines, fluid in fissure)
5.2.3.2.3. Severe (pulmonary edema)
5.2.3.3. Pleural effusion
5.2.3.4. Other major abnormality (e.g., pneumonia, mass)

5.3. Lab results
5.3.1. Timing of the lab specimen
5.3.1.1. Relative to symptom onset
5.3.1.2. Relative to clinical characteristics
5.3.2. Serum chemistry and blood analysis results, including the units of measurement
5.3.2.1. Blood urea nitrogen or urea
5.3.2.2. Creatinine
5.3.2.3. GFR
5.3.2.4. Sodium
5.3.2.5. Hemoglobin
5.3.2.6. Natriuretic peptides
5.3.2.6.1. Manufacturer name
5.3.2.6.2. BNP
5.3.2.6.3. NT-proBNP
5.3.2.7. Cardiac biomarkers
5.3.2.7.1. Assay type (high sensitivity or normal) and manufacturer
5.3.2.7.2. Established cutoffs for normal values and method by which they were derived
5.3.2.8. Other AHFS biomarkers may be considered
5.3.2.8.1. Midregional pro-atrial natriuretic peptide, adrenomedullin

5.3.3. Specimen collection and handling procedures
5.3.3.1. Detailed methods of sample handling and compliance with manufacturer recommendations
5.3.3.2. Phlebotomy tubes used (reagent), centrifugation, etc.
5.3.3.3. Assay performed individually or batched, run at time of blood draw or delayed
5.3.3.4. Location (e.g., at bedside, ED stat laboratory, offsite research laboratory)
5.3.3.5. Storage (e.g., sample frozen within how many hours of draw, flash frozen on liquid nitrogen, freezing temperature, length of time frozen)

5.3.4. Marker performance relative to defined outcomes. This is a core requirement if the primary objective of the investigation is assessment of marker performance; otherwise, it is a supplemental criterion.
5.3.4.1. Sensitivity, specificity, positive predictive value, negative predictive value, and likelihood ratios with 95% confidence intervals
5.3.4.2. Receiver-operating characteristic curve data
5.3.4.2.1. Optimal operating point and how defined
5.3.4.2.2. Interval likelihood ratios

5.3.5. Relevant confounders for the assays being used. This is a core requirement if the primary objective of the investigation is assessment of marker performance; otherwise, it is a supplemental criterion.
5.3.5.1. Proportion of patients with renal insufficiency
5.3.5.2. Body mass index for natriuretic peptide testing

6. Patient Course
Patient course can be quite variable for patients presenting with AHFS. Medications administered as well as the timing of interventions may have a significant impact on patient course and disposition. Medications and interventions should be reported according to whether they were given early in the patient course or as secondary treatment after initial therapy had not produced an adequate response. Further categorization is also needed to delineate whether the medication was given as a primary treatment or a secondary (preventive) measure.

6.1. ED and hospital course
6.1.1. ED disposition
6.1.1.1. Discharge
6.1.1.2. Observation unit admission
6.1.1.3. Inpatient admission
6.1.1.4. Left ED against medical advice
6.1.1.5. Died in ED
6.1.1.6. Transferred

6.1.2. Observation unit management
6.1.2.1. System
6.1.2.1.1. Virtual unit or defined space
6.1.2.1.2. Level of monitoring (i.e., telemetry)
6.1.2.1.3. Number of beds
6.1.2.1.4. Eligibility criteria for unit admission
6.1.2.1.5. Heart failure specific or general
6.1.2.2. Personnel
6.1.2.2.1. The training characteristics of personnel primarily responsible for the patient undergoing observation care
6.1.2.3. Treatment protocols
6.1.2.3.1. Therapeutic protocols or algorithms in use for patients undergoing observation care
6.1.2.3.2. Rate of protocol compliance
6.1.2.4. The length of time under observation status

6.1.2.5. Disposition
6.1.2.5.1. Home
6.1.2.5.1.1. Discharge criteria, including any consultation requirements
6.1.2.5.2. Inpatient admission
6.1.2.5.3. Left observation unit against medical advice
6.1.2.5.4. Died in observation unit

6.1.3. Inpatient admission
6.1.3.1. Intensive care unit/cardiac care unit
6.1.3.2. Telemetry
6.1.3.3. Unmonitored floor bed
6.1.3.4. Transferred

6.1.3.2. Inpatient disposition
6.1.3.2.1. Home
6.1.3.2.2. Died in hospital
6.1.3.2.3. Hospice
6.1.3.2.4. Transferred to another hospital
6.1.3.2.5. Extended care facility

6.2. Therapeutics and interventions
6.2.1. Pharmacological therapeutics
6.2.1.1. Aspirin
6.2.1.2. Vasoactives
   6.2.1.2.1. Nitroglycerin and route (intravenous, topical, sublingual)
   6.2.1.2.2. Nitroprusside
   6.2.1.2.3. Nesiritide
   6.2.1.2.4. Phenylephrine
   6.2.1.2.5. Norepinephrine
   6.2.1.2.6. Epinephrine
   6.2.1.2.7. Dopamine

6.2.1.3. Inotropic agents
   6.2.1.3.1. Dobutamine
   6.2.1.3.2. Milrinone
   6.2.1.3.3. Levosimendan

6.2.1.4. Diuretics
   6.2.1.4.1. Name of diuretic
   6.2.1.4.2. Dose
   6.2.1.4.3. Mode of administration (oral, intravenous bolus, or continuous infusion)

6.2.1.5. Beta-blockers
6.2.1.6. Angiotensin-converting enzyme inhibitors
6.2.1.7. Angiotensin receptor blockers
6.2.1.8. Aldosterone antagonists
6.2.1.9. Morphine
6.2.1.10. Atropine
6.2.1.11. Antiarrhythmic (e.g., adenosine, amiodarone)
6.2.1.12. Antithrombins (e.g., unfractionated heparin, low molecular weight heparin, direct thrombin inhibitors)
6.2.1.13. Others

6.2.2. Nonpharmacological therapeutics

6.2.3. Interventions
   6.2.3.1. Primary
   6.2.3.2. Secondary/preventive
   6.2.3.3. Noninvasive ventilation (continuous positive airway pressure/bilevel positive airway pressure)
   6.2.3.4. Intubation
   6.2.3.5. Electrical cardioversion
   6.2.3.6. Defibrillation
   6.2.3.7. Right heart catheter, both as a 1-time procedure to obtain diagnostic data and a pulmonary artery catheter to follow response to therapy
   6.2.3.8. Left heart catheterization
   6.2.3.9. Single-chamber pacemaker
   6.2.3.10. Biventricular pacemaker
   6.2.3.11. Implantable cardioverter-defibrillator
   6.2.3.12. Percutaneous coronary intervention
   6.2.3.13. Balloon pump
   6.2.3.14. Ultrafiltration
   6.2.3.15. Percutaneous cardiopulmonary support
   6.2.3.16. Ventricular assist device
   6.2.3.17. Transplantation
   6.2.3.18. Others
   6.2.4. Timing of therapy or intervention relative to presentation
   6.2.4.1. Pre-hospital
   6.2.4.2. Early (within first 12 to 24 h)
   6.2.4.3. Late (after first 24 h)
   6.2.5. Route of administration of therapy
   6.2.5.1. Oral
   6.2.5.2. Sublingual
   6.2.5.3. Intravenous
   6.2.5.4. Intramuscular/subcutaneous
   6.2.6. Endotracheal tube
   6.2.7. Dose of therapy

6.3. Response to treatment
   6.3.1. Total urinary output
   6.3.2. Weight change during hospitalization
   6.3.3. Total input/output during hospitalization
   6.3.4. Laboratory values before discharge
   6.3.4.1. Blood urea nitrogen
   6.3.4.2. Creatinine
   6.3.4.3. GFR
   6.3.4.4. Sodium
   6.3.4.5. Potassium
   6.3.4.6. BNP/NT-proBNP
   6.3.4.7. Hemoglobin
   6.3.5. Hemodynamic values before discharge
   6.3.5.1. Blood pressure (systolic and diastolic)
   6.3.5.2. Heart rate
   6.3.6. Respiratory status before discharge
   6.3.6.1. Respiratory rate
   6.3.6.2. Oxygen saturation including amount of supplemental oxygen
   6.3.7. Jugular venous pressure before discharge

7. Outcomes
Hospitalization for AHFS is a significant marker for post-discharge events (i.e., rehospitalization or mortality). However, very few studies have been conducted that looked at short-term outcomes based on acute management. Development and establishment of short-term outcome goals or targets is a current area of investigational research, balancing the needs of clinicians, investigators, and regulatory agencies. For studies of the management and evaluation of AHFS, therefore, the definition of outcomes appropriate to the study’s purpose should be reported.

7.1. Safety and efficacy endpoints
    7.1.1. Mortality
       7.1.1.1. Days from presentation (e.g., 5 days, 7 days, 30 days, 180 days)
    7.1.2. Morbidity
       7.1.2.1. Worsening heart failure (as defined for the study)
       7.1.2.2. Days alive and out of hospital
    7.1.3. Resource utilization
       7.1.3.1. Lengths of stay
### Table 1 Core Components

1. Screening and recruitment
   1.1. Specific ages for inclusion and exclusion
   1.2. Procedure for identifying population to be screened
   1.3. Method of screening
   1.4. Account for patients screened and included in and excluded from the study

2. Demographics
   2.1. Sex
   2.2. Age
   2.3. Race

3. Previous cardiac diagnosis, risk factors, and medical history
   3.1. Hypertension
   3.2. Diabetes mellitus
   3.3. Smoking
   3.4. Hypercholesterolemia or hyperlipidemia
   3.5. Acute myocardial infarction
   3.6. Known cardiovascular disease
     3.6.1. Heart failure
     3.6.1.1. Etiology of heart failure (if known)
     3.6.1.2. Preserved or reduced systolic function and definition used
     3.6.2. Coronary artery disease.
   3.7. Previous objective evaluations for heart failure
      3.7.1. Previous ejection fraction or current ejection fraction
      3.7.1.1. Method used to assess ejection fraction (e.g., echocardiography, catheterization, nuclear study)
   3.8. Home treatment

4. Acute presentation
   4.1. Dyspnea
     4.1.1. Respiratory rate
     4.1.2. Oxygen saturation
   4.2. Hemodynamic status
     4.2.1. Blood pressure
     4.2.2. Heart rate
   4.3. Precipitating factors

5. Test reporting
   5.1. ECG
     5.1.1. Person(s) interpreting the ECGs
     5.1.2. Timing of the ECG relative to presentation
     5.1.3. Findings suggestive of acute coronary syndrome
   5.2. Chest radiograph
     5.2.1. Procedure used for imaging
     5.2.2. Person(s) interpreting the chest radiograph
     5.2.3. Findings on the chest radiograph
   5.3. Lab results
     5.3.1. Timing of the lab specimen
     5.3.2. Serum chemistry and blood analysis results, including the units of measurement
     5.3.3. Specimen collection and handling procedures
     5.3.4. Marker performance relative to defined outcomes. This is a core requirement if the primary objective of the investigation is assessment of marker performance; otherwise, it is a supplemental criterion.
     5.3.5. Relevant confounders for the assays being used. This is a core requirement if the primary objective of the investigation is assessment of marker performance; otherwise, it is a supplemental criterion.

### Table 1 Continued

6. Patient course
   6.1. ED and hospital course
     6.1.1. ED disposition
     6.1.2. Observation unit management
     6.1.2.5. Disposition
     6.1.3. Inpatient admission
     6.1.3.2. Inpatient disposition
   6.2. Therapeutics and interventions
     6.2.1. Pharmacological therapeutics
     6.2.2. Nonpharmacological therapeutics
     6.2.3. Interventions
       6.2.3.1. Primary
       6.2.3.2. Secondary/preventive
   6.3. Response to treatment
     6.3.8. Therapeutics given
     6.3.9. Interventions
       6.3.9.1. Primary
       6.3.9.2. Secondary/preventive
   6.4. Response to treatment

7. Outcomes
   7.1. Safety and efficacy endpoints
     7.1.1. Mortality
     7.1.2. Morbidity

8. Follow-up
   8.1. Duration of follow-up
   8.2. Clinical follow-up and timing
   8.3. Research follow-up

ECG = electrocardiogram; ED = emergency department.

7.1.3.2. Costs
7.1.3.3. Recidivism

7.2. Organ protection/preservation/improvement

7.2.1. Cardiac
   7.2.1.1. Biomarkers
   7.2.1.2. ECG
   7.2.1.3. Echocardiographic indices
   7.2.1.4. Hemodynamic (specify invasive or noninvasive)
   7.2.1.5. Serious arrhythmia (atrial fibrillation/flutter, ventricular tachycardia, ventricular fibrillation)

7.2.2. Renal
   7.2.2.1. Blood urea nitrogen
   7.2.2.2. Creatinine
   7.2.2.3. Creatinine clearance or GFR (specify method of calculation if estimated)
   7.2.2.4. Novel biomarkers
   7.2.2.5. Other

7.2.3. Stroke
   7.2.3.1. Hemorrhagic
   7.2.3.2. Nonhemorrhagic

7.3. Interventions
   7.3.1. Pharmacological
     7.3.1.1. Need for rescue therapy (define)
   7.3.2. Surgical
   7.3.3. Procedural

Continued in next column
7.3.4. Airway management (endotracheal tube, non-invasive ventilation)

7.4. Symptoms and signs (distinguish between physician assessed and patient assessed)

7.4.1. Dyspnea

7.4.2. Jugular venous pressure

7.4.3. Rales

7.4.4. Edema

7.4.5. Other

7.5. Quality of life

7.5.1. Quality of life questionnaires (e.g., Kansas City Cardiomyopathy Questionnaire)

7.6. Response to therapy

7.6.1. Body weight

7.6.2. Urine output

7.6.3. Functional capacity (e.g., 6-min walk test)

7.6.4. Other

7.7. Composite endpoints: each component needs to be specifically defined

7.7.1. Global rank: events prioritized by importance (e.g., death > rehospitalization > biomarker elevation); this method provides an opportunity for more subjects to experience an “endpoint”

7.7.2. Breakdown of individual endpoints of composite measure

8. Follow-up

There are limited data available regarding a recommended time to follow-up after an ED visit or hospitalization for AHFS (13,32–34). Access to follow-up care may vary depending on several factors including availability of heart failure specialty or primary care clinics and the patient’s insurance status. Poor outpatient follow-up may exert considerable confounding on research outcomes. Patients with an inability to obtain appropriate medications or clinical follow-up may experience adverse events independent of the research intervention being applied. Both clinical and research follow-up should therefore be reported.

8.1. Duration of follow-up

8.1.1. Start point of follow-up period

8.1.1.1. Presentation

8.1.1.2. In-hospital/treatment events

8.1.1.3. Discharge

8.2. Clinical follow-up and timing

8.2.1. Access to and attendance at care providers during the follow-up period

8.2.1.1. Primary care

8.2.1.2. Cardiologist

8.2.1.3. Heart failure specialty clinic

8.3. Research follow-up

8.3.1. Methodology

8.3.1.1. Telephone or in person

8.3.1.2. Patient or proxy

8.3.1.3. Use of medical record review

8.3.1.3.1. Primary follow-up method

8.3.1.3.2. Supplementary to contact

8.3.1.3.3. Confirmatory of reported events

8.3.1.4. Insurance/claims data

8.3.1.5. National registry/Social Security Death Index

8.3.2. Proportion lost to follow-up

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Key Words: acute heart failure ■ emergency department ■ reporting criteria ■ study design.