Nursing research in heart failure care: a position statement of the american association of heart failure nurses (AAHFN)

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Introduction

Nursing research is driven by a vision toward optimizing the health and wellbeing of individuals, families and the community. When considering heart failure (HF), nurse scientists bring a unique perspective of the human condition that contributes greatly to the areas of wellness, disease prevention and management. Nurse scientists use interdisciplinary, bio-behavioral and translational approaches to promote health, advance quality healthcare delivery and optimize health outcomes in HF. With aging of the population and increasing prevalence of HF, it is more important now than at any other time in history for nursing research in HF to be robust and focused on areas of inquiry that promote the best patient outcomes. The American Association of Heart Failure Nurses (AAHFN) recognizes the need for a tailored position statement to assist researchers, funding institutions and policymakers to contribute to our knowledge base in HF, and to move HF clinical advancements and outcomes forward. The aims of this statement are to: 1) describe epidemiological changes in HF care over time and the societal impact of HF today; 2) describe global advancements and outcomes in HF nursing research and effects on clinical care; 3) discuss the direction of HF nursing research, the incorporation of precision care and potential new developments and gaps; and 4) put forth a call for action with recommendations for types of research designs that should be used to promote validity, sustainability and funding of future HF nursing research.

Epidemiology and Impact of Heart Failure

The clinical syndrome of HF is a common and severe result of several cardiovascular and extra-cardiovascular diseases. HF is a progressive syndrome that typically develops over the course of many years and is associated with impaired physical functioning and quality of life as well as high symptom burden.[1] The worldwide prevalence of HF is rising,[1-3] and despite improvements in available therapies, HF affects millions of people and it continues to be associated with frequent healthcare utilization and premature mortality. In secular trends in HF epidemiology, patients are more likely to have multi-morbidity (i.e. co-occurrence of 2 or more chronic conditions) that includes several risk factors, such as diabetes, kidney disease, obesity, and are increasingly more likely to have a cause of death from non-cardiovascular causes.[4]

Incidence and prevalence

Globally and in the U.S., HF incidence rates can vary depending on the study population and diagnostic criteria used to estimate parameters.[5] Over the last decade, however, similar trends were found in HF incidence and prevalence rates between the U.S. and Europe.[6] For example, a large cross-sectional study of more than 2 million people living in the greater Stockholm region of Sweden in 2010 found the adjusted incidence of HF was 3.7 per 1000 person years among men and women,[7] which represented about a relative 24% decrease from 2006.[7] Using data from private and Medicare Advantage health plans (> 100 million persons), the incidence of HF was 2.1 per 1000 person years between 2006 and 2014.[8] In the Olmsted County Minnesota cohort, age- and sex-adjusted incidence of HF was 2.19 per 1000 in 2010,[2] representing a decline in the incidence of HF with reduced ejection fraction (HFrEF) (-45.1%; 95% CI, -33.0% to -55.0%) and HF with preserved ejection fraction (HFpEF) (-27.9%; 95% CI, -12.9% to -40.3%) compared with data from 2000. Slower HFpEF decline may be attributed to

the high rates of uncontrolled hypertension, diabetes and obesity that place patients at risk for HFpEF.[2]

In contrast to declining HF incidence, prevalence of HF is rising. Based on data from the U.S. National Health and Nutrition Examination Survey (NHANES) between 2009-2012, approximately 6.5 million individuals are living with HF.[9] This represents an 11% increase from a similar report in 2013.[10] Because the risk of HF rises with age and there is an increase in the aging population as well as patients with HF are living longer,[1-3] it is anticipated that most European nations will experience a similar rise in the HF prevalence.[6] In 2012 and based upon the NHANES database, HF prevalence in individuals greater than 20 years of age was 3.2% for Black women, 2.8% for Black men, 2.2% for both White men and women and 2.1% for Hispanic men and women.[9] In studies that included Asian Americans, authors reported low HF incidence, HF related hospitalization and mortality rates compared to Black, White and Hispanics.[8] In one national population database, NHANES, sex differences appear to be reversing and compared to men, more women (≥ 20 years) are living with HF, are hospitalized for HF and have greater mortality rates.[9] In other databases, higher hospitalization rates for women with HF living in the community compared to men were reported.[8] Finally, changing trends in HF incidence and prevalence apply to HF patients with HFrEF and those with HFpEF, however data regarding secular trends in incidence and prevalence of HFpEF were less widespread. It is important to note that clinical characteristics are different between these groups, with HFpEF more often being older, female, having comorbidities such as hypertension, diabetes, obesity and atrial fibrillation all of the latter can impact rates of mortality and hospitalization.[11]

Etiology and risk factors

Although hypertension and coronary artery disease remain leading causes of HF, diabetes mellitus and obesity are now common elements of HF etiology.[5] The occurrence and contributions of different etiologies to the development of HF can vary across populations and racial/ethnic groups. Importantly though, the contemporary patient with HF will have multiple risk factors and the burden of risk factors in patients with established HF increases over time.[5] In addition, the contemporary patient with HF will have multi-morbidity: the number of patients with 5 or more chronic conditions increased from 42.1% in 1988-94 to 58.0% in 2003-2008.[5]

In summary, the incidence of HF is declining but prevalence is increasing because of the aging population worldwide, such that at least in the U.S. by 2030 it is predicted that there will be nearly 8 million adults with HF.[9] A few important changes in the epidemiology of HF include multi-morbidity, increased hospitalization rates due to non-cardiovascular causes and increased use of long-term care facilities. Disparities continue to prevail based on race. with Black individuals experiencing an increased risk for HF, increased rate of hospitalizations and more chronic conditions such as chronic kidney disease. Although some changes in epidemiology were positive, there are still areas where further exploration is necessary.

Nursing Research Contribution in Advancing HF Care

Nurse scientists have made strong contributions to improving the care of patients with HF. Advancements most prominently have been in areas of organization of care (e.g., disease management, person-centered care), understanding mechanisms and related factors to facilitate the participation of patients in their care (self-care), and nursing interventions to improve outcomes in patients with HF.

Organization of care

In a series of randomized trials worldwide, effectiveness of HF disease management approaches were demonstrated; such as, home-based interventions and multidisciplinary clinics.[12] In a Cochrane collaboration, several models were effective: (1) case management interventions (intense monitoring of patients following discharge often involving telephone follow up and home visits); (2) clinic interventions (follow up in a HF clinic) and (3) multidisciplinary interventions (holistic approach bridging the gap between hospital admission and discharge home delivered by a team).[13] Among patients with HF who were previously hospitalized, case management interventions led by HF nurses reduced readmissions and length of stay.[14]

A variety of HF management models have been evaluated. A single model that would universally fit all health care systems and patient populations is unrealistic. Further, in recent large scaled studies, some HF models were unsuccessful at improving outcomes; authors suggested a need for a unique approach to HF management.[15,16] In a recent meta-analysis, comparative effectiveness of transitional care services after hospital discharge for HF were described. Nurse home visits and HF clinics decreased all-cause mortality. Along with nurse case management, the three program types also reduced all-cause readmissions, with no significant difference in comparative effectiveness.[12] The three programs use a person-centered approach; and this approach) was found to advance concordance between care providers and patients on treatment plans, and to improve health outcomes and patient satisfaction.[17]

Transitional care programs vary widely. Programs typically begin prior to hospital discharge and include the nurses' role in HF education, communication and coordination among team members, as well as implementing individualized care plans.[18] In an integrative review of HF transitional care programs, improvements were found in quality of life, hospital readmission

rates and cost of care.[18] Types of interventions most successful in decreasing readmissions and maintaining or reducing cost utilized home visits in combination with telephone contact.[18] Transitional programs that offered high- or moderate-intensity services reported decreased mortality, and both high- and low-intensity programs were reported to decrease HF re-hospitalization.[13] Many factors were associated with worsening HF symptoms leading to hospitalization that could benefit from integrated, interdisciplinary, patient-centered transition of care programs.[19]

Self-care in patients with HF

A large body of evidence has been published regarding self-care of patients with HF.[20] In a recent meta-analysis, authors suggested that self-management interventions could have a beneficial effect on time to HF-related hospitalization, all-cause death and HF-related hospitalization.[21] Self-care influences both medical and patient-centered outcomes in HF. Patients with HF who reported more effective self-care had better quality of life, lower mortality and readmission rates than those who report poor self-care.[22-24] Characteristics of patients with HF who were less likely to engage in self-care behaviors included disease severity, limited knowledge, comorbidities, cognitive and emotional dysfunction and coping strategies.[25] Factors that complicated self-care among patients with HF were lack and overload of caregiver support, limited social networks, living in rural areas, limited financial capacity and interaction with peers.[26]

Nursing Interventions to improve Outcomes

Research has contributed to the evidence base of 'nursing interventions' to improve outcomes in patients with HF. Patient and family education has been examined and is frequently reported as an intervention in nursing research. Current HF guidelines recommend patient and

family education and include recommended educational topics.[3,27] One-hour of standardized patient education provided by a nurse educator at the time of hospital discharge increased self-care, adherence to treatment recommendations, reduced cost of care and risk of re-hospitalization.[28] In addition, hospitalized patients with HF who were educated using "teach-back" methods retained significantly more information and correctly answered HF specific questions.[29] Further research is warranted to examine educational methods, timing, duration, effect on adherence and hospitalization, especially since in a meta-analysis of transition care programs, services that provided 'patient education alone' did not reduce all-cause rehospitalization.[12]

A growing body of literature exists on the effectiveness of a variety of exercise interventions for patients with HF in which nurses maintain a key role, such as a cardiac rehabilitation program for HF patients,[30] home walking programs,[31-34] home-based tele-monitored cardiac rehabilitation,[35,36] tai chi[37,38] and yoga.[39,40] Other interventions that have been tested for effects to improve patient outcomes in HF include those aimed at improving cognitive function. In preliminary studies, cognitive training led to small improvements in cognitive function,[41,42] as well as positive effects on engagement in HF self-care[43] and functional outcomes such as instrumental activities of daily living (e.g., medication taking, grocery shopping) that may result in reduced healthcare costs.[44] In addition, family relationships among patients with HF and their caregivers were examined in several studies; investigators described both positive and neutral results of family based interventions.[45-49]

This summary of HF nursing research provides a limited overview of the current body of knowledge and significant impact findings had on patients, families and providers. It also highlights gaps in the literature that may serve to guide future research (**Table 1**).

Precision Medicine and Heart Failure Nursing Research

The term precision medicine is defined by the National Institutes of Nursing Research (NINR) (2015) and Institute of Medicine (IOM) (2015) as an initiative to "*discover the right treatment, for the right patient, at the right time*," and "*discover and understand factors that either contribute to or protect one against common diseases*."[50,51] Another term that is commonly used is precision health, which is defined as providing the right intervention to the right person or population at the right time.[52] Nurse scientists and advanced practice nurses can influence precision medicine by integrating omics into HF research to understand relevant biology, variances and environmental exposures, and by advocating that patients with HF consider enrolling in research that involves omics. It also is important for nurse scientists to consider how gaps in knowledge and solutions to common health problems can be identified through appropriated handling of big data (i.e. data characterized by high volume, velocity, variety, veracity and value).[53] Although big data may entail using retrospective or prospective databases, it is important to be aware that limitations apply to research in any field.

Gaps and Future Directions for HF Research

As a means of increasing the rigor, transparency and potential translation of HF research to practice, we have identified several gaps and key future directions that should be considered in conducting HF research.

Appropriate Representation

Similar to other elements of human health, we know more about HF in older Caucasian men compared with other populations that are in many instances at greater risk for developing HF and/or suffer worse outcomes.[54] Research in HF should entail balance by sex (lifetime risk of developing HF is equivalent by sex) and also entail the involvement of racial and ethnic

minorities equal to if not greater than distributions in the greater populous.[55] Research in HF should also involve other marginalized populations, including but not limited to those with language, economic and/or health literacy disadvantages. There are also several clinical phenotypes of HF based on etiology (e.g. ischemic and non-ischemic), heart function (e.g. preserved vs. reduced ejection fraction) and/or severity that should be fully considered in the sampling frame of HF research. To move HF science forward, we must view HF as being much more complex than as it manifests in older Caucasian men with ischemic disease and participants that are from the whole social spectrum instead of only highly motivated patients who are interested in making behavioral changes.

Newer and Better Trial Designs

Simple randomized control trials (RCTs) have long been viewed as the gold standard in biomedical research. Particularly in the early phase of intervention development and testing, enrichment strategies (i.e. prospective strategies to decrease heterogeneity, prognostic enrichment strategies (choosing patients with a greater likelihood of having a clinical event), and predictive enrichment strategies (choosing patients more likely to respond to the intervention) similar to those involved with drug trials should be considered.[56] There are several other trial designs that have advantages over RCTs that should be considered as design alternatives/complements in the advancement of HF research. For example, several adaptive trial designs allow for the rapid identification of therapies that have a therapeutic effect and patient populations for whom therapies are appropriate. Bayesian adaptive methods entail the modification of protocols based on information gained during the trial (e.g. outcomes and adverse events) and can include changes in intervention dosing and delivery, sample size and group allocation within a pre-specified but adaptive trial protocol.[57,58] Sequential Multiple

Assignment Randomized Trial (SMART) designs embed sequential decision rules into adaptive trial protocols based on participant response; hence, participant treatment is individualized to some degree.[59-61] The continuum between explanatory trial (i.e. RCT undertaken in an ideal setting to have the best chance to demonstrate efficacy) and pragmatic trial (RCT undertaken in the "real world" and intended to help support clinical and policy decisions) should also be considered fully in the design of HF trials;[62] indeed, there are nine dimensions to be considered when assessing the degree of pragmatism of a trial (i.e. eligibility, criteria, recruitment, setting, organization, flexibility in delivery, flexibility in adherence, follow-up, primary outcome, and primary analytic strategy).[63] More generally, there are strategies that should be considered to strengthen trials including but not limited to block randomization with random block sizes (particularly in small trials)[64] and effective implementation of run-in periods.[65]

Larger and More Robust Non-Experimental Studies

Data derived from small cross-sectional studies are often not generalizable and therefore do not contribute to advancement of HF science. We need larger "real world" effectiveness (observational) studies to validate prior efficacy (trial) work. Moreover, much greater attention needs to be paid toward methods used to mitigate bias in observational studies.[66] One concern that is pervasive in non-experimental HF studies is the presentation of unadjusted or minimally-adjusted analysis. Unadjusted models in non-experimental research (including unadjusted Actor-Partner Interdependence Models in dyadic research[67]) are the most biased and potentially misleading because they fail to take into consideration any other factor(s) that may influence relationships of interest. Simply put, unadjusted analyses should only be performed in non-experimental studies as a means of describing the sample and presenting compulsory preliminary results. When comparisons are made between/among subgroups in non-experimental designs,

robust methods of mitigating comparative bias should be employed. The rate of false discovery[68] must be taken into account when conducting multiple analyses from the same non-experimental study. Strong consideration should be given as to the logic and consequences of merging data from multiple non-experimental studies.[69-75] Merging raw data from multiple non-experimental studies should be justified scientifically and with transparency in how results might be different when considering studies to be independent. Finally, an overwhelming proportion of HF research led by nurses is not only non-experimental but also cross-sectional. Hence, it is highly recommended that non-experimental research be longitudinal to gain greater insight into how phenomena change over time and allow for participants to have more exposure to HF and its treatment.

Improved characterization and description of HF subjects

The American College of Cardiology and American Heart Association has recommended the inclusion of certain subject characteristics to facilitate cross-sectional comparison among studies and generalizability to clinical practice.[76] Therefore, it is important that subject inclusion criteria detail parameters such as ejection fraction, HF duration, etiology, and common treatments. In the setting of advanced HF, other myocardial parameters such as ventricular filling pressures may be important to include. Other recommended clinical variables to include are laboratory (e.g. sodium, hemoglobin) and diagnostic test results (e.g. pulmonary function parameters). For details on Clinical Data Standards, please see:

http://circ.ahajournals.org/content/circulationaha/112/12/1888.full.pdf).[76] The use of tools such as the Seattle Heart Failure Model, can also add to the characterization of the HF subject cohort, in addition to providing information about prognosis.[77]

Full Scope of Outcomes

Although a preponderance of HF research led by nurses has focused on behavioral or patient-oriented outcomes, many others should be considered. Specifically, clinical outcomes such as survival or event risk, economic (e.g. cost-consequence and cost-effectiveness et al. following the Consolidated Health Economic Evaluation Reporting Standards statement[77]), and biological outcome (including strong and evidence-based multi-marker strategies that represent genomics and other biological technologies) should be given equal consideration as behavioral outcomes in HF research. It is also important, when appropriate to use physiologic parameters or variables to support and demonstrate a biologic link to the effects of an intervention.

Harmonization of Measures

Since the advent of the Patient-Reported Outcomes Measurement Information System (PROMIS)[78] and the PROsetta stone (http://www.prosettastone.org), it is recommended that patient-reported outcome measurement be harmonized across HF studies. Instead of developing new questionnaires and measures, consideration should be given to employing existing measures with established properties and generalizability to other populations.[79,80] Finally, more work needs to be done in psychometric evaluation to ensure that systematic measurement bias is not influencing how patient-reported measures are interpreted.[81]

Examination of Heterogeneity

Irrespective of the design of research, heterogeneity is something to be anticipated and explored. In RCTs, heterogeneity in treatment effects is common and should be explored as a means of identifying who might benefit most and least from a particular intervention.[70] In non-experimental research, the identification of previously unobserved subgroups is often an a priori strategy to identify opportunities for intervention development and/or allocation.[82] Finally, heterogeneity is something that should be expected, quantified and sufficiently addressed in

meta-analyses.[83] Hence, it is recommended that heterogeneity in HF research be explored to help identify subgroups with differential response (actual or potential) to therapies.

Discussion

HF is a major global health problem. Although the incidence of HF is declining, prevalence continues to increase.[84] HF research transcends the continuum of care from prevention, disease management to end of life, and seeks to meet the needs of a diverse population. Nurses are integral to the care of patients with HF, and their families. There is a growing body of scientific nursing knowledge that includes but is not limited to, models and organization of HF care, facilitation of patients' participation in their care (self-care) and interventions to improve patient outcomes. However, quality, rigorous research is needed to improve the lives of patients and their families while advancing nursing science. A small sampling of areas needing further exploration in HF is detailed in **Table 2**. Finally, translation of HF research to practice is critical to ensuring patients and their families receive holistic evidence-based care. Several gaps in the nursing literature and key future directions have been identified that should be given full consideration when engaging in HF research.

It is the position of the AAHFN and the Research Consortium that:

1. The body of nursing science in HF is developed through research and research outcomes that serve to promote the care of patients with HF, their families and the nursing profession.

2. Nurse scientists (both clinical and bench researchers) who study HF require access to the necessary resources that include, but are not limited to financial support to produce quality scientific outcomes.

3. Research is not performed in isolation and requires collaboration with nurse scientists and other disciplines across the continuum of care, while harmonizing data measures to ensure strong, timely, quality HF studies are developed.

4. Nursing research should be led by nurses who maintain knowledge and education to develop and complete high quality, rigorous research studies, and include students and novice researchers when possible to mentor and develop future nurse scientists.

5. Nurses' at all educational levels should remain current in advances in the science and seek to translate findings into practice.

6. Nursing research findings must be disseminated in peer-reviewed journals so that new HF knowledge can be shared and reviewed globally.

Conclusion

Despite advances in technology and medical therapy, HF continues to impact patients and families worldwide. HF nursing research is critical to managing and improving patient outcomes while promoting the nursing profession.

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Table 1. Future Areas of Inquiry in Heart Failure Research

Category	Topics
Advanced Treatment	• Identification and referral • Advanced treatment outcomes
Epidemiology	• Causes of death • Gender and ethnic differences • Frequency of hospitalizations and readmissions • Multi-morbidities • Chronic kidney disease and heart failure
Education of patients and families	• Educational method and/or combinations • Educational timing, duration and dosing • Depth and breadth of education on specific HF and related content
HF Management	• Disease management programs • Risk stratification • Coordination and transition of care to other agencies • Comorbidities • Care across the continuum, preventative, palliative and hospice • E health
Self-Care	• Cognition and health literary • Symptom recognition, symptom management; evaluation of symptoms after intervening • Facilitators of adherence to treatment recommendations • Dietary recommendations • Exercise response (dyspnea, diaphoresis, elevated heart rate) • Stress management • Self-assessment of sleep disordered breathing to increase sleep assessment and intervention
Family/Caregiver	• Family relationships and support • Caregiver burden

Table 2. Examples of Heart Failure Nursing Research Needs

Predictors of or Interventions that Improve or Enhance…	Considerations (text) and Areas of Focus (bullets)
Self-care maintenance behaviors • Smoking cessation • Regular physical activity; • Medication adherence; • Dietary sodium consumption	Previous research focused on patient characteristics, heart failure (HF) etiology and characteristics, comorbid conditions, health literacy, and knowledge as predictors of self-care behavior adherence, but there is no consensus on factors that can be used as predictors • Cultural, environmental, general health status and other patient perspectives and factors • Formal clinical diagnosis and knowledge about HF • Benefits of learning and coping education strategies • Improving adherence
Remote monitoring and messaging	• Clinical decision system for evaluating worsening status • Clinical decision system for improving status • Biosensor systems efficacy • Expansion, adoption and effectiveness • Improving adherence to remote monitoring
Early HF re-hospitalization	Many predictive models are available today but most have insufficient sensitivity, specificity (area under the curve) or other accuracy features that limit clinical use • Data-driven machine learning that provides phenome-wide selection strategies and fine tuning • Critical points on patient pathways including barriers to evidence-based practices
In-hospital worsening HF	Many reports provide descriptions of rescue therapies and management strategies that include medications, cardiac assist devices, renal therapies and surgery; but reports are secondary analyses from acute HF randomized controlled trials that may not be fully generalizable to all hospitalized patients • Treatment based on NYHA Class and HF Stage • Need best pharmacologic treatment strategies
Admission (versus discharge) from emergency department (ED) care	Many ED physicians admit the majority of patients treated; rather than evaluating carefully for observation unit care and discharge, or ED discharge with early follow-up • At risk characteristics or biomarkers for poor clinical outcomes and quality of life • Transition from ED to home (or other disposition site)
HF education and HF knowledge	Research on HF patient education themes are well documented but gaps in strategies that lead to effectiveness are not as prevalent • Skills in relation to self-care self-efficacy • Patient and family alignment in understanding • Cognitive function and memory enhancement • Using teach back • Psychological and emotional factors
Readiness for end-of-life care	• Multi-professional training needs • Clinical decision support