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Abstract

Introduction: Congestive Heart failure is a significant cause of morbidity and mortality in Australia. Accurate data for the Northern Territory and Indigenous Australians is not presently available. The economic burden of this chronic cardiovascular disease is felt by all funding bodies and it still remains unclear what impact current measures have on preventing the ongoing disease burden and how much of this filters down to more remote areas. Clear differentials also exist in rural areas including a larger Indigenous community, greater disease burden, differing aetiologies for heart failure as well as service and infrastructure discrepancies. It is becoming increasingly clear that urban solutions will not affect regional outcomes. To understand regional issues relevant to heart failure management, an understanding of the key performance indicators in that setting is critical.

Methods and Analysis: The **N**orthern **T**erritory **H**eart **F**ailure **I**nitiative **– C**linical **A**udit **(NTHFI-CA)**, is a prospective registry of acute heart failure admissions over a 12 month period across the 2 main Northern Territory tertiary hospitals. The study collects information across 6 domains and 5 dimensions of health care. The study aims to set in place an evidenced and reproducible audit system for heart failure and inform the developing heart failure disease management programme. The outcomes it is hoped will assist the development of solutions to narrow the outcomes divide between remote and urban Australia and between Indigenous and Non-Indigenous Australians, should they exist. A combination of descriptive statistics and mixed effects modelling will be used to analyse data.

Ethics and Dissemination: This study has been approved by respective ethics committees of both the admitting institutions. All participants will be provided a written informed consent which will be completed prior to enrolment in the study. The study results will be disseminated through local and international health conferences and peer reviewed manuscripts.

Introduction

The congestive heart failure (CHF) syndrome is the leading cause for admissions and is in the top three causes for mortality in the Western World. It is associated with significant morbidity, impacts on individual's quality of life and through the necessity of frequent medical and allied health interventions, prescription of pharmacological agents and recurrent hospitalizations, is a source of stress on health resources. Guidelines based care improves outcomes but challenges exist in implementation. Neglecting this resource intensive investment leads to poor outcomes and so the cycle perpetuates. CHF is speculated, as no accurate prospective data is available, to be higher in the Northern Territory (NT) and among Indigenous Australians. The recent **C**entral **A**ustralian **S**econdary **P**revention of **A**cute Coronary Syndromes (**CASPA**) study highlighted a significant burden of CHF, greater among the Indigenous communities[1], confirming earlier studies of under representation nationally[2]. These works have highlighted several key indicators relevant for the NT[1-14]:

1) There is a *high burden* of CHF that cannot be explained by *traditional risk factors* alone. Among the Indigenous population, given that social factors influence the risk of CHF the excess in mortality is most likely to be multifactorial in origin, and have its foundations in the economic, social, physiological, psychological and educational disadvantages[1].
2) There appears a greater burden of CHF related to rheumatic and *non-ischemic aetiology*, which is reversible and has a better prognosis when treatment is delivered or preventive measures enforced [2-5,14].
3) There appears a greater burden of CHF with *co-morbidities* among Indigenous clients, which requires greater resources to deliver comprehensive care[2].
4) There are significant *barriers and differentials* in *access* to appropriate, acceptable and evidence based medical care and preventative measures for Indigenous and remote clients. New delivery methods are important as CHF can largely be delivered as community based care[13-24].
5) There is significant *delay in presentation* and receipt of acute care during periods of decompensation and for geographical and other reasons delay of definitive therapies or procedures[24,25].
6) There is poor *uptake* of post-discharge services such as cardiac rehabilitation and at present unknown demographics that will assist implementation of remote allied health or technological based solutions[3,13].
7) Unique *geography* - the NT consists of a vast area with 2 major public hospitals in Alice Springs and Darwin servicing 230,000 clients, approximately 70% live within the urban proximity. Specialist services reside at the tertiary hospitals with satellite district hospitals in several smaller townships supporting a small number of visiting specialists. Service planning must take this into account[3,14].
8) *External validity* - adherence to guidelines early in hospital admission can improve outcomes, however not all groups meet trial conditions in remote areas nor are trial conditions for dosing strategies reproducible [27,28]. A consensus on therapeutics strategies is needed.

Lack of accurate prospective data for the listed points makes it difficult to accurately develop a tailored, yet comprehensive HF program. Developing tools to gather evidence require adhering to standards for validity and reproducibility, which are also lacking. This study is focused on understanding the current evidence base for quantifying health care systems and informing the design of diagnostic and management clinical audits that would form the backbone for the direction of CHF disease management systems within a NT context. We thus propose to study the quality and outcomes of care for patients admitted with acute decompensated heart failure (ADHF). We aim to develop key clinical and process of care performance indicators (KPI) and translate these findings for improved service delivery if and where deficiencies are highlighted. This paper describes the rationale for the NTHFI-CA design.

Methods

Aims and Scientific Hypotheses

The NTHFI-CA survey was designed with 4 major objectives: Firstly to develop validated and reproducible key clinical and process of care indicators for the comprehensive measurement of quality of care and outcomes for clients admitted with ADHF. In this we aim to measure for the clients, the proportion meeting standardised clinical outcomes, process outcomes and defined targets of secondary prevention and compare by age, ethnicity, sex and place of usual residence. For the health system, identify failures of the health care system in relation to timely acute care and to the provision of secondary CHF care, particularly for indigenous and remote clients; Secondly to develop a system of data collection and reporting, that can be used for ongoing quality assessment and improvement across the care continuum; Thirdly, the results of the first two objectives are hoped will help tailor a pilot intervention study similar to the ongoing nurse led intervention developed around the CASPA study findings; Fourthly to accumulate sufficient epidemiology and implementation focused information to steer future action in the provision, monitoring and development of guidelines based quality CHF care for rural, urban, Indigenous and Non Indigenous clients. We hypothesize that patients presenting with ADHF are expected to have: a disproportionate representation of Indigenous clients with advanced systolic impairment; excess of alcohol, ischemic or rheumatic aetiology; greater co-morbidities in diabetes, hypertension, lipid abnormalities and/or renal insufficiency, and with other noncardiac co-morbidities; delayed presentations for Indigenous and remote clients; We hypothesize that treatment for Indigenous and remote clients: are likely suboptimal for the stage of HF; have fewer clinical interventions and support compared to their urban counterparts; are less likely to receive novel therapeutic options or enrolled in multicentre trials; are more likely to have their HF managed without regular cardiology specialist input.

Projected Outcomes

We anticipate several outcomes from this work: Firstly, *identification* of the points of weaknesses in the hospital and community health centre systems that impact on both urban, rural, indigenous and non-indigenous clients and hopefully lead to the development of focused service improvement models across this care continuum; Secondly, to *link* with a number of collaborative research projects assessing barriers to care for indigenous clients suffering with heart diseases; Thirdly, lead to the development of *ongoing and sustainable* quality improvement practices and monitoring within hospital and PHC services across the region; Fourthly, help develop, trial and implement *standardised* medical discharge summaries and care plans during hospital stay and following discharge; Fifthly, explore the potential *contribution* of poor systems of care to the high level of illness faced by Indigenous people; and Finally, assessment of the potential barriers that may exist for primary and secondary *prevention* for CHF. These goals should initially drive improved service delivery and subsequently provide a baseline for evaluating ongoing service outcomes on which to base future acute and preventive program development and inform the development of alternative models of secondary prevention for NT clients with CHF.

Protocol

The project is made up of two specific stages. *Stage 1* is the collaborative development of suitable KPI covering both process and outcome measures across the continuum of care and *Stage 2,* involves 2 phases*,* is the

development of appropriate, feasible data collection tools and their subsequent measurement in both hospital and primary health care settings.

The Development of Appropriate Clinical Indicators (Stage 1)

We conducted an extensive literature review with key words “heart failure or acute heart failure or chronic heart failure or congestive heart failure”; and “database or study design or study rationale or registry”; and “Data Collection/ or Quality Indicators, Health Care/ or Management Audit/ or performance indicators.mp or Healthcare Disparities/Quality Assurance, Health Care/ or Quality of Health Care/ or Quality Indicators, Health Care/ or quality of care indicators.mp or "Outcome and Process Assessment (Health Care)"/ or process of care.mp”. Published and established existing KPI for measuring the quality and outcomes of care for patients experiencing ADHF were collated[6-12, 29-40]. The CASPA study KPI was used as a template. Within 6 domains and 5 dimensions of care KPI were added or rested on this template using the ACC/AHA attributes of performance measures[31]. Addition or removal required consensus of the principal investigator and one co-investigator. Uniform agreement by all co-investigators was required for accepting the final measures (Box 1 and 2). Acute Coronary Syndrome, (as an aetiology for ischemic cardiomyopathies or aggravator of existing cardiomyopathies) and KPI that were deemed not to add any additional benefit on what was already known from CASPA were also rested.

Study Design and Registry (Stage 2)

The NTHFI-CA registry is a prospective observational cohort study designed to examine the performance of health systems in relation to the acute management and secondary prevention of ADHF in patients admitted to two regional hospitals in the NT, Royal Darwin Hospital (RDH) and Alice Springs Hospital ASH) commencing September 2013 and followed for 12 months ending September 2015. Performance will be measured against currently available evidence based guidelines for the treatment and secondary prevention CHF[4,6-9-11,29,33-38]. Data collected will enter NTHFI-CA study registry located at Baker IDI Heart and Diabetes Institute, Alice Springs. All documentation relating to study participants will be treated in accordance with National Statement of Ethical Conduct in Human Research[41].

Eligibility Criteria: Patients admitted to either hospital with the diagnosis of HF (ICD-10CM I42.0-I42.8,143.0, 150.0-150.9) will be eligible for the prospective case note audit. The subjects will also be drawn from in-patients who develop acute symptoms whilst in hospital for other reasons. Further assessment will also involve the generation of lists ICD CM I00-I02, I05-I09, I10-I15, I20-I28, I30-I41, I44-I49, I70-I89, I95-I99 (complicated with acute heart failure) for cross checking of initial coding and recording of outcome variables. Subjects will be considered eligible if the review of medical records demonstrates that they in fact have suffered an ADHF based on ACC/AHA and National Health Data Dictionary standardised definitions

Exclusion Criteria: Patients will be excluded if they die within 24 hours of admission or do not usually reside within either region or whom no follow-up data can be obtained, however, these clients will still provide baseline incidence data. Cases that do not fulfil the case definition of ADHF on review of the notes will also be excluded, and recorded but will not form baseline data.

Population/Recruitment of Subjects: A dedicated research assistant will recruit consecutive patients who present acutely to either hospital or transferred from remote indigenous communities from the emergency clinical screen and medical admission lists for. Of these, clients who are Aboriginal, are non-Aboriginal, have a documented

urban residence and reside in remote communities with will be followed. The subjects will also be drawn from in-patients who develop acute symptoms whilst in hospital for other reasons. Flyers will be posted in emergency, wards, intensive care and a brief presentation made to the medical and nursing staff at relevant units. Referrals from hospital staff in this form will be a secondary recruitment strategy. For retrospective audit lists of individuals will be generated through hospital separation and CCU admissions data for the years 2011 and 2012. The approved research assistant in each site will perform this. An independent physician will review uncertain cases.

Data Collection and Storage: Data will be collected on a standardised case note extraction form developed during phase one of the project. Information will be accessed through multiple sources including hospital records, primary health care clinic records, specialist databases, and record systems maintained by visiting district medical officers. The period of interest for data collection will be 0-12 months after discharge following documented ADHF. Data definitions will be standardised and widely accepted case and outcome definitions as outlined in the ACC Clinical Data Standards[9-11,31-37]. All cases that demonstrate ambiguity in data definitions or outcome data will initially be discussed with site investigator, if ambiguity persists, the principal investigator and a locally convened panel of the research team will review, and consensus sought.

Measurement of Performance: Phase 1 involves prospectively auditing admitted clients hospital records. Phase 2 involves further assessment of performance and will involve the auditing of client records held at remote community health centres, urban primary health care centres, specialists' records, hospital records, outpatient and cardiac rehabilitation files. Files are coded and stored by 3 health providers, NT Department of Health and Community Services (DHCS - ASH/RDH), Primary health care records (PHC) and NT Cardiac Services Pty Ltd. NT DHCS hospital separation data, hospital records coding and storage of data follows a nationwide format. PHC records will also be accessed to complete the secondary prevention and follow-up components of the audit and is subject to variability. NT Cardiac, main provider of cardiac diagnostics and outpatient care, databases and coronary intervention information systems holds a range of clinical and cardiac investigation/intervention (angiography, coronary stenting, echocardiography, stress testing) information. This information will be used to complete the data collection sheet for each patient file. Denominator and numerator values for KPI will be based on standardised values from ACC/AHA guidelines, local laboratory specification for biochemical tests and Australian accrediting bodies for invasive and non-invasive investigations. Overall performance will be compared to the National benchmark for CHF outcomes. As this is subject to change the broad principals will include CSANZ, Heart Foundation and locally published studies that involve a public tertiary HF referral centre from any of the 6 states in Australia. We will also seek the opinion of several local leading HF clinicians should there be issues standardising these benchmarks.

Participant Follow-up: Clients will be followed up to determine subsequent hospitalization, major medical events and interventions. Similar ICD codes for acute CHF will be used for screening Information at 1, 6 and 12 months. Data extraction will include a combination of case notes review, medical databases, contact with PHC and clients directly. Consent for this will be obtained during the initial recruitment.

End Points: The main indicators we are measuring cover a range of domains across the spectrum of care for people with ADHF. In brief variables include:

- Baseline
  - Demographics: Age, sex, usual place of residence, ethnicity;
  - Background: Past medical history of CHF and treatments, known risk factors and co morbidities;
  - Symptom onset: Time, nature, location, first point of contact with PHC, delay times to care.

- Pre-Hospital Management: Appropriate medical/paramedical assessment, provision of pre-hospital nitrates, diuretics, ventilation and analgesia;
- Emergency Department: presentation, delays, biochemistry, investigations (CXR, ECG, echocardiography), therapeutics (assisted ventilation, IV nitrates or diuretics); risk stratification.
- Admission Details: clinical examination, investigations, management, complications during admission, performance of phase I rehabilitation;
- Discharge: Discharge diagnosis, discharge status, medication regime, referral to phase II cardiac rehabilitation, discharge planning and referral to primary health care provider;
- Outpatients:
  - Cardiac rehabilitation: Attendance and completion of cardiac rehabilitation.
  - Secondary Prevention: risk factor modification, care plan, cardiac education received, measurement of and achievements of specified target goals for HF and prevention of risk factors related to aetiology (eg CVD i.e. smoking cessation, lipid control, BP control), complications.
  - Self- Management.
  - Depression - PHQ9.
  - Outcomes: re-admission, major cardiovascular and non-cardiovascular events, mortality.
  - IT and Telecommunications: availability, access and type of mobile phone and Internet platforms.

Special Ethical Consideration and Adverse Events: Cultural and religious issues surrounding confidentiality and storage of human tissue are of significant importance for Indigenous clients. The NT is also host to a diverse multiethnic population. We have thus chosen not to store samples for future use. We have sought specific support from key Indigenous Community groups, NT-DHCS, Cardiac Services, Remote and Primary Health Services, Independent Health Services and Indigenous Health Services, in advance. As primarily a hospital and clinic file audit, this proposal does not directly broach the issues of reciprocity, respect, equality, responsibility, survival and protection, which are critical in Indigenous research, confirmation of which was obtained through the ethics submission. We do not anticipate any other adverse events. *We have received full ethics approval to conduct the study by Central Australia and Top End Human Research Committees.*

Training and Standardization

This project requires access to data housed and maintained by NT DHCS and NT Cardiac Services. Hospital Separation Data, Hospital Records and PHC Records will be sought from NT DHCS and will be arranged through PI's in Darwin. In the event that PHC records are housed within independent services (non-DHCS clinics) appropriate consultation will be undertaken as requested by the independent services themselves. Formalised consent processes as directed by Independent services will be followed. If they wish to perform the audit themselves, as a training and quality assurance process, appropriate training and support will be provided by the research team. All staff recording information will be briefed by training staff from the CASPA study and undergo education in variability or data recording, ambiguous data and differing case records, ICD-10 classification, ACC/AHA guidelines for KPI[28] and NHMRC good clinical practice as the minimum requirement. Addressing ambiguity has been discussed under data collection and storage.

Expected Sample Size

On the basis of generated hospital separation and CCU statistics, 2009, for ASH of 113 and RDH of 450 patients, the sample population will be approximately 150 patients with ADHF at ASH and 500 matched at RDH (27) in the

time period 2009. Of the ASH separations, 99 (88%) are identified as being indigenous. The matched (ethnicity and gender) RDH sample extrapolates to 180 (40%), Aboriginal clients in phase II. As data will be collected on three separate occasions for each patient, a robust dataset is expected to identify any significant associations between predictors and patient outcomes. Findings from this investigation will also inform the development of more testable hypotheses in future studies and appropriate sample sizes.

Statistical considerations

All generated data will be entered into and analysed with SPSS v 11.5. Initial data analysis will be conducted to assess for data quality including allowable ranges, data structure and errors. Descriptive statistics for baseline participant characteristics, diagnostics and therapeutics within highlighted domains will be calculated and presented as means (standard deviation), interquartile range (IQR) for continuous data and count (percent) for categorical data. Univariate between group analyses will be performed using t tests for continuous variables, and χ^2 tests of association for categorical variables. For study outcome measures, a Type 1 error rate o alpha=0.05 will be used to test for statistical significance. A generalised mixed-effects model approach will be used in the analysis of repeated measures for continuous and categorical outcomes. Mixed-effects models take into account the inter-individual differences in intra-individual change with repeated responses and use all the available data on each subject. Mixed models are also unaffected by randomly missing data and therefore do not require imputation methods[46]. The model building strategy will include fitting nested models by sequentially adding blocks of predictor variables: socio-demographics, co-morbid disorders and factors related to health service interventions. Interaction terms that are considered to be potentially important from a clinical perspective will be tested and remain in final models if significant. Predicted estimates of outcomes at each time point will be calculated using fitted models of the data in order to examine patterns of individual change. To interpret effect sizes and precision for categorical outcomes, odds ratios and confidence intervals will be calculated.

Discussion

The NTHFI-CA represents one of a few opportunities offered for longitudinal studies designed to extract data that informs service development. Information gathered has to be relevant for current and future needs. It is difficult to determine service factors beyond 5 yearly intervals. To compensate for this, there have been measures taken to set infrastructure and standardise protocols to facilitate episodic updates in information as well as ensuring reproducibility of study design and implementation. With the actual study design a series of steps were taken. The first step was establishing basic principles for defining the disease (Box 1, Appendix A). The second step involved standardising principles for attributes in KPI i.e. care dimensions (Box 2.1, Appendix B & C) and the study care domains to be tested, in this case 6 (Box 2.2). The third step involved addressing the broad NT health goals and research conduct in Indigenous population to steer implementation within 5 key priorities (Box 2.3). The fourth step is design of disease management systems in the NT context from the available evidence (Box 2.4, Appendix D). The specific details are explored.

The ACC/AHA has released several position statements to standardise the process of developing, assessing, implementing performance measures and disease management systems[30-33]. From this consensus driven platform, we identified the target disease, population and explored standardised measures that inform the observation for the required time period. The NTHFI-CA is defined for the all stages and causes of CHF, for NT resident population who receive care within 6 domains of treatment. This broad definition partly relates to uncertainties on actual CHF demographics, and as the yearly admission are unlikely to exceed 500, will not lead to significant difficulties in enrolment. To determine the performance measures we again explored the position statement that initially rated 27 potential measures on 13 dimensions using a 5-point Likert scales[31], following a process that advanced measures if it received full committee support with score of at least 3, and concluding with 7 inpatient and 12 outpatients' measures. Five dimensions of care, encompassing diagnostics, patient education (including prognosis and aetiology), treatment, and self-management (for inpatient and outpatient) and monitoring of disease status (for outpatients only) were deemed important[31]. This statement did not however focus on outcomes as the design was shaped to assist physicians improve care. We have included outcomes, as this is the strongest indicator for funding for vulnerable groups beyond the conventional block funding models. To determine the final KPI several additional points were considered:

I. *Existing Studies:* Several recent databases stand as land mark achievements in HF epidemiology and have confirmed clinical understanding of evidence base and positive outcomes[9-11,35,37,43]. Interestingly Krumholz etal[30] pointed out a disparity between what is conventionally accepted evidence and its generalisabilty. This is particularly so for the NT where there are significant non-traditional factors that impact on the delivery of evidence based care and affect outcomes. While it would be unreasonable to propose reconducting large CHF studies to incorporate an increasingly diverse group of patients we have come to realise that at the heart of these matters is developing an intrinsic understanding of the underlying regional demographic differences and service delivery dynamics to be able to formulate informed decisions in implementing the necessary measures, be they simple or more complex. Developing the necessary KPI in these settings is a challenge as there is a divide between perceived optimal care and, realistic and deliverable care that is in fact optimal for the region. From this it was evident that some measures needed to be rested (e.g. treatment optimization) and others added (e.g. the dimension of technology).

II. *NT Experience:* The CASPA study was ground breaking in the sense that it allowed for the first time exploration of ACS/cardiovascular KPI in Central Australia. The list was formulated from an extensive search of available national and international clinical guidelines, national health priority area indicators and reports and with reference to National Health Performance Committee guidelines and further augmented by performance measures used in published quality improvement projects. 3 priorities - process of care, target achievement and outcome indicators for the treatment and prevention were generated. This list underwent scrutiny by 60 key stakeholders, key external content experts and the research team through mailed questionnaires and a workshop convened in Alice Springs. Each stakeholder was asked to grade each potential indicator according to a number of criteria: Strength of evidence; feasibility of measurement; plausibility of effects from quality improvement; impact on outcomes; and an assessment of the overall utility of the measure. Results were collated and analysed for each indicator (overall grading) and for each of the five criteria across each indicator. Indicators that were graded as high priority, frequently recorded, very plausible and will have a large impact or better were included in the final list (average score on grading scale ≥ 4.0). Indicators that demonstrate an across criteria grade of less than 4, but was assessed by key stakeholders as a high or essential priority within the overall (utility) rating, were scrutinised by the project team and included as decided by consensus. Data specifications were then developed according to internationally standardised definitions. Subsequent data collection tools were developed and piloted in a number of hospital and PHC records (n=20) and implemented. The spill over knowledge assisted greatly in the NTHFI-CA design.

Combining this local and international experience, with the standardized ACC position[31], a conceptual framework KPI reflecting 6 critical domains for treatment delivery and 5 principal dimensions of care evolved (Box 2). All these well established performance measures were individually scrutinised and included or rested. Level of evidence was the predominant scrutinizing theme in the second phase. The less validated 'local knowledge' and NT health priorities were additional considerations. Study investigators made the decisions on these. Several less well established indicators were included through recent understanding and development of self-management and IT based solutions[14]. In direct contrast to intervention themed databases focus on specifics in the treatment dimension was given a lower priority (see appendix in ref 34, 35). Box 4 describes this in greater detail.

Further rationale for specific KPI inclusion or exclusion are as follows: Domain 1: Demographics are at the heart of this study. Validated KPI derived from CASPA were used to extract race, culture, language and support networks; Further expansion was made in the dimension of HF aetiology with emphasis on ischemic, hypertensive as well as rheumatic and alcohol induced causes. Data on tertiary referral centres were collected, as there were 2 main cardiac surgical referral hospitals. Decision referral patterns vary with the treating physician practices as well as waiting list and urgency. It is established that decisions on percutaneous or surgical revascularisation and valvular restoration or replacement differs at these sites on physician, group consensus and expertise at the respective sites. Details on primary care physician, pharmacy, residence and principal next of kin were deemed important as local and ethnicity were deemed factors in service uptake and delivery. Furthermore access to primary care could determine - admission, readmission burden and early measures to prevent deterioration; Domain 2 -5: A comprehensive past medical history of all systems were included to establish the overall need for chronic medical service needs and factors preventing use or uptake of HF pharmacology, cardiac rehabilitation or referral for invasive management. Biochemistry details were included to establish pattern of establishing HF aetiology and outpatient risk for adverse events. Methods for estimating eGFR was obtained as much recent work raises validity of estimated measures with illness and demographics,

which subsequently alter prescribing practices and outcomes[11,12,44]. KPI for depression were expanded as a high burden was noted in CASPA, this also being a significant factor in many dimensions of self-care and compliance. In hospital, discharge and outpatient indicators were designed to reflect potential blocks to maximising proven pharmacological prescription and access to cardiac rehabilitation, at the core of these were reasons for non-prescription or sub-therapeutic prescription. The actual specifics on medication titration across all domains were rested. It is noted that care and resources are needed to titrate many variables in CHF care, for e.g. ββ and ACE-I (Appendix E &F). This information can be extrapolated from frequency of contact with medical practitioner and central pharmacy prescription slips. Appropriate early therapeutics - to prevent further heart muscle damage, good symptom relief and minimising iatrogenic adverse effects such as renal dysfunction and electrolyte derangements is within the control of the health systems and builds client confidence, and is considered vital, this dimension was included. Domain 6: Overall we felt, in the community, that the greatest value in the performance measures related to 2 critical aspects - impacts on the overall health system (strain and morale) and contributors to poor outcomes (client and non-client). Post hospital access to services and blocks to referrals (non client) and self-management (client) are factors related to efficiency, planning and client education. Investment in these dimensions would not add increase strain on resources, with potential benefit.

Data collection instrument was via Case Report Forms (CRF) designed for a combination of retrospective and prospective audit from combination of several studies CASPA and WHICH. The Baker IDI, Flinders University, and SAHMRI have extensive track record in electronic CRF. This was greatly beneficial and reduced challenges faced for stage 2. At present much research work is conducted through the Menzies School of Health Research. As part of this initiative we have began the process of developing dedicated office to conduct studies across the cardiac and renal axis. Part of this also involved staff training in good clinical practice and transfer of knowledge form partners to stand as an independent entity*.

Indigenous health in the NT requires special focus. Australia has seen the first Indigenous premier in 2013 and a measured but controversial statement of removing the Indigenous ministerial portfolio was “there are numerous ministers for many areas and one for all Indigenous affairs”. Current sentiments that move away from race based programs are encouraged but with caution. We clarify that out approach does not target any specific communities but is based on needs. It is unfortunate that disadvantaged communities are also marginalised in large studies partly for language, cultural and perceived compliance issues. In this case the Indigenous community represent a significant group in Australian society who have despairingly worse outcomes. The desire to preserve ones traditional culture in an ever modernising world proves huge challenges for these communities and health systems. Poor understanding could lead to stereotyping that could brand some behaviour as recalcitrant, adding to the vicious circle. Respecting these beliefs and tailoring care in lieu of these factors we were able to advance the CASPA study. This was done through acknowledgement as several sensitive areas in the ethics application; *Equality* - The overarching aims of the research project is based within a framework driven by questions of equality in the provision of health care across the continuum for all patients regardless of ethnicity, gender or age, and one based on need as demonstrated by clinical determinants; *Survival and Protection* - We also recognise that chronic disease research and epidemiology has tended to contribute to deficit approaches to individual pathology; that is disease is due to bad behaviour. Less focus has been afforded the potential successes and

* *Information on our partners and expertise can be found on the web or via corresponding author.*

failures in health systems, as contributors to differential outcomes for populations based on ethnicity; *Respect* - "We feel that information generated within this project and the processes developed have the potential to contribute to community directed health service redevelopment and quality improvement activities; *Reciprocity* - We feel that this work may identify failures in health systems and therefore identify obligations that are being unmet by systems themselves; *Responsibility* - Re-framing the gaze of health inequality, from individual focused deficits to system failures stands as the key principle on which this extensive work is based, and is a direct effort at ensuring that exploring health inequalities does not undermine and harm Indigenous individuals and communities. These principles may play great importance to future research practices in these areas.

Dissemination: Measuring performance is not an end in its own right and clinical indicators and their measurement alone are not sufficient to change behaviour in service provision and quality improvement. They must be supplemented with key educational activities, processes to sustain continuous monitoring and assessment and to inform policy development on a local and regional level. Clearly defined dissemination processes and involvement of Aboriginal Health Workers, hospital and community based nurses, allied health professionals and clinicians are essential if practice is to change. The CASPA ACS intervention study is currently underway. It may likely have a spill over effect on the NTHFI-CA study. Areas that are subject to exploration include the RDH subset, non-included in the intervention and non-ischemic cardiomyopathies and non-ischemic readmissions of previously diagnosed ischemic cardiomyopathies. It is also hoped that the NTHFI-CA data will help development of an intervention with the eventual objectives of: engagement of service providers, data coders, quality improvement staff, NGO's (NHF NT Division, Healthy Living NT), Division of General Practice/Primary Health Care and consumer representatives in the development phase of the project so as to ensure alignment between proposed indicators and local needs; provision of continuous and sustained feedback of results to all levels of service provision. This will also include discussion of KPI targets and performance in individual work units and services, and the identification of deficits in service provision and data collection processes within health services across the continuum of care. This data will be used to plan for improved processes within a local context, and will be collated to provide recommendations to quality improvement practices and audit across the NT; the dissemination of key findings through key advisory/research institutions We also have been in negotiations for the broader applicability of the findings of and tools utilised within this project with the Australian Collaborative Project (which seeks to measure PHC performance). This stands as a critical method of project outcome dissemination.

Limitations:

Conducting clinical studies in the NT is in itself a limitation; firstly, the realization of non-traditional risks factors, which impact on management; secondly, as there are few benchmarks as comparators; and finally shortfalls in research funding and infrastructure. While no system has the perfect mix of resource input to match service needs to answer this question, for this region, there will be components within many aspects of the study that is hypothesis generating, compared to the mainstream. Nonetheless following the accepted consensus and providing enough information to allow reproducibility is accepted as a positive means for overcoming this limitation. Examples of this were resting KPI that collate in depth information on medication dosing as per randomized clinical trials and large HF databases[30-38]. This study will not address whether clinical trial prescribing practices are achieved, instead we are keen to determine if there is a system in place to facilitate this, which will be answered. The infrastructure is also in place for the next step to determine if this can occur. We note that RCT

level outcomes relate to achieving prescribing practices in the trials. As examples Appendix E/F, highlight differences in just 2 medications. *As noted in, ββ titration is ideally done at 2 weekly intervals and may not need biochemistry, while ACE-I can be done at 3-7 daily and usually require assessment of basic biochemistry. Addition of aldosterone blockers and other agents are further complexities*. We are hopeful that relevant information on this will help steer the next phase, an intervention audit. This study relied on lessons from ACS study conducted greater than 5 years ago. Unanticipated changes that cannot be standardized could act as confounders, which will only be revealed in time; e.g. is potential drop off rate during follow-up. In the standardization of design – we did not use 5 point Likert scale, as the number of NT consultants was only 4. In addition the CHF task force position was comprehensive[31]. Finally, clinical practice guidelines are well established, as Krumholtz stated "guidelines are written in a spirit of suggesting diagnostic or therapeutic interventions for patients in most circumstances. Accordingly, significant judgment by clinicians is required to adapt these guidelines to the care of individual patients" to ensure accountability in these judgments an evidenced based process is important. The standardizing of clinical judgment and interpretation of guidelines remains contentious and may be more noticeable with fewer cardiologists. As such we intentionally left the criteria for KPI reference broad. This will be narrowed, as lessons are learnt and early data are analyzed. This should aid more focused and detailed assessments in the future.

⁎ We have not provided treatment pathways for AICD/CRT/ other pharmacotherapies. These are available from several optimizing databases (34,35,37).

Conclusion

Achieving optimal care in the remote setting is no different from urban settings. The ability to provide a continuum of care from presentation to post discharge requires activation of proven KPI at each level of care. The significant differences in remote care revolve around the interaction of service infrastructure, personnel, disease burden and cultural sensitivities. As such the outcomes limiting factors are variable and require exploration. The potential gains of these findings in implementing early and later secondary prevention of CHF and its sequelae are undisputed. In addition, little information exists on the provision and outcomes for CHF initiatives for indigenous populations, which are a significant client base in the remote setting. Even less is known about the post-discharge care. The extent to which care is sub-optimal and the acute and long-term HF management among Aboriginal clients could be contributing to the large and growing cardiovascular mortality differentials seen between Aboriginal and non-Aboriginal clients. Thus the development of meaningful, sustainable public health, clinical and continuous quality improvement policy in the provision of CHF care in the NT requires urgent attention, and must be used to drive the development of better service delivery at both the individual and health system levels. It is anticipated that this work will highlight key areas of disparity and inform the implementation of an intervention study.

Abbreviations

ACS – Acute coronary syndrome

ADHF – Acute decompensated heart failure

ASH – Alice Springs Hospital

CASPA – Central Australian Secondary Prevention of Acute Coronary Syndrome Study

CASPA-HF – Central Australian Secondary Prevention of Acute Heart Failure Study

CHF – Congestive Heart Failure

CVD – Cardiovascular Disease

DHCS – Department of Health and Community Services

ICD – International Classification of Diseases

KPI – Key Performance Indicators

NT – Northern Territory

PHC – Primary Health Care

RDH – Royal Darwin Hospital

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Competing Interests

None

Contributorship

All authorship credit are be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. The current authors meet conditions 1, 2, and 3.

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BOX 1: ICD 10 Diseases of the circulatory system. Primary screening includes codes I42, I43 and I50. Secondary screening involved ADHF during index admission with highlighted codes

ICD-10-CM Code	Primary classification (I42,I43,I50) Description
I42.0	Dilated Cardomyopathy
I42.1	Chronic systolic (congestive) heart failure
I42.2	Acute on chronic systolic (congestive) heart failure
I42.3	Unspecified diastolic (congestive) heart failure
I42.4	Acute diastolic (congestive) heart failure
I42.5	Chronic diastolic (congestive) heart failure
I42.6	Acute on chronic diastolic (congestive) heart failure
I42.8	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I43	Cardiomyopathy is diseases classified elsewhere
I50.1	Left heart failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.9	Heart failure, unspecified

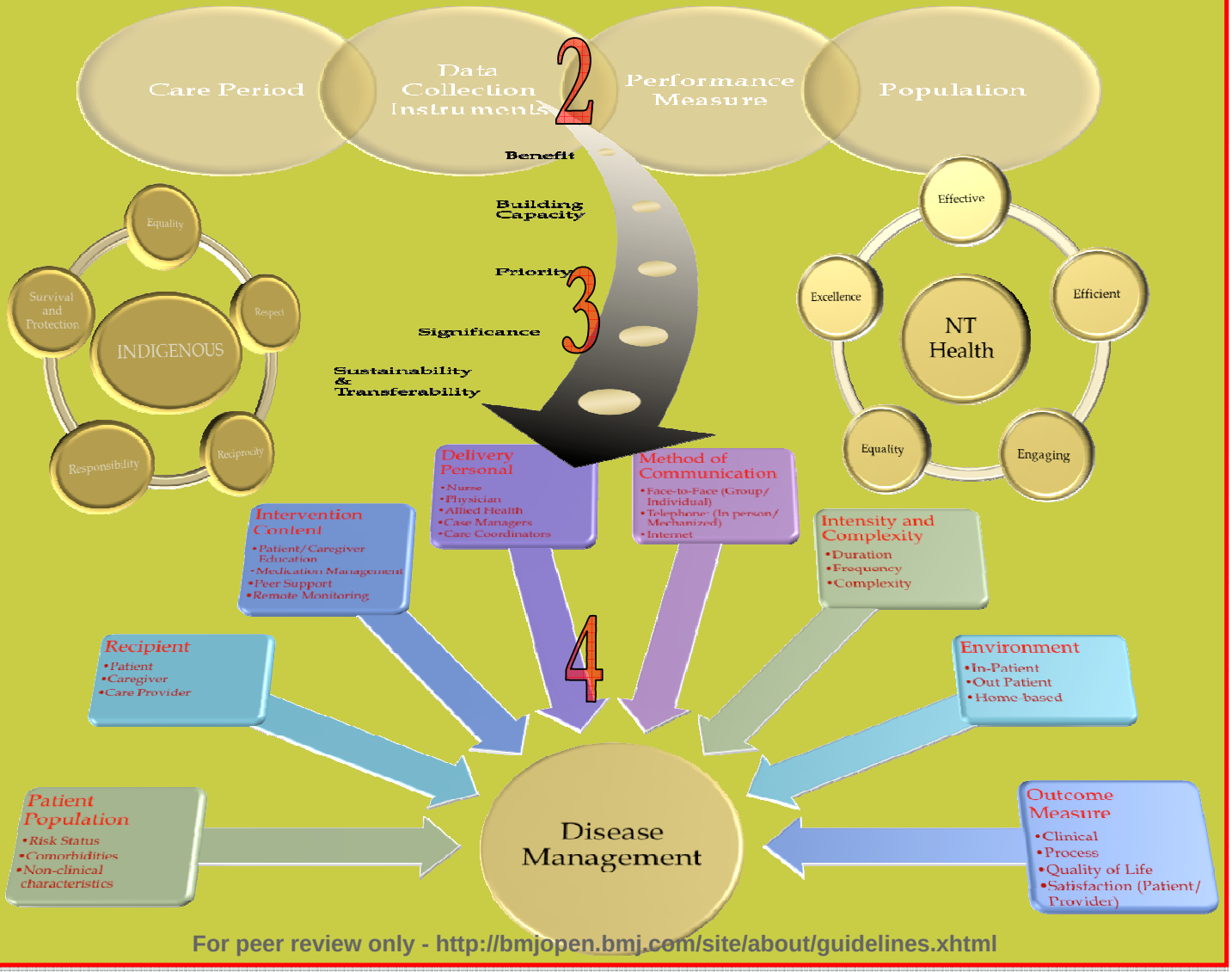
ICD-10-CM Code	Secondary Acute Heart Failure with these Admission Codes Description
I00-I02	Acute Rheumatic Fever
I05-I09	Chronic Rheumatic Heart Disease
I10-I15	Hypertensive Heart Diseases
I20-I25	Ischemic Heart Diseases
I26-I28	Pulmonary Heart Disease and Diseases of Pulmonary Circulation
I30-I32	Pericardial Diseases
I33-	Endocardial Diseases
I34-I39	Nonrheumatic valve disorders
I40-I41	Myocarditis
I44-I45	Conduction system Disorders
I46	Cardiac Arrest
I47-I49	Tachyarrhytmias
I70-I79	Diseases of arteries, arterioles and capillaries
I80-I89	Diseases of veins, lymphatic vessels and lymph nodes, not elsewhere classified
I95-I99	Other and unspecified disorders of the circulatory system

BOX 2 Design of the NTHFI-CA involved 4 steps: 1 – using a set of standardised principles (blue box) and their attributes (green box) we formulated outlines for each performance attribute (final column). CASPA shaped many aspects of design and implementation attributes; 2 - four basic factors shaped the broad study outline; 3 – highlights the ethical considerations for studies in the NT; 4 – broad disease management goals for which performance measures hope to inform. (Ref 30-33)

Principles and Recommendations From the AHA's Expert Panel on Disease Management
1. The main goal of disease management should be to improve the quality of care and patient outcomes.
2. Scientifically derived, peer-reviewed guidelines should be the basis of all disease management programs. These guidelines should be evidence based and consensus driven.
3. Disease management programs should help increase adherence to treatment plans based on the best available evidence.
4. Disease management programs should include consensus-driven performance measures.
5. All disease management efforts must include ongoing and scientifically based evaluations, including clinical outcomes.
6. Disease management programs should exist within an integrated and comprehensive system of care in which the patient–provider relationship is central.
7. To ensure optimal patient outcomes, disease management programs should address the complexities of medical comorbidities.
8. Disease management programs should be developed for all populations and should particularly address members of underserved or vulnerable populations.
9. Organizations involved in disease management should scrupulously address potential conflicts of interest.

1

ACC/AHA Attributes for Satisfactory Performance Measures (Appendix A/B)		NTHFI-CA
Useful in improving patient outcomes	1. Evidence-based 2. Interpretable 3. Actionable	Ref 28-30
Measure design	1. Denominator precisely defined	Inclusion/Exclusion
	2. Numerator precisely defined	Yes CHF
	3. Validity - Face validity - Content validity - Construct validity	CASPA
	4. Reliability	CASPA
Measure implementation	1. Feasibility - Reasonable effort - Reasonable cost - Reasonable time period for collection	CASPA
Overall assessment		Pending



Box 3 Trial Protocol and Study Pathways

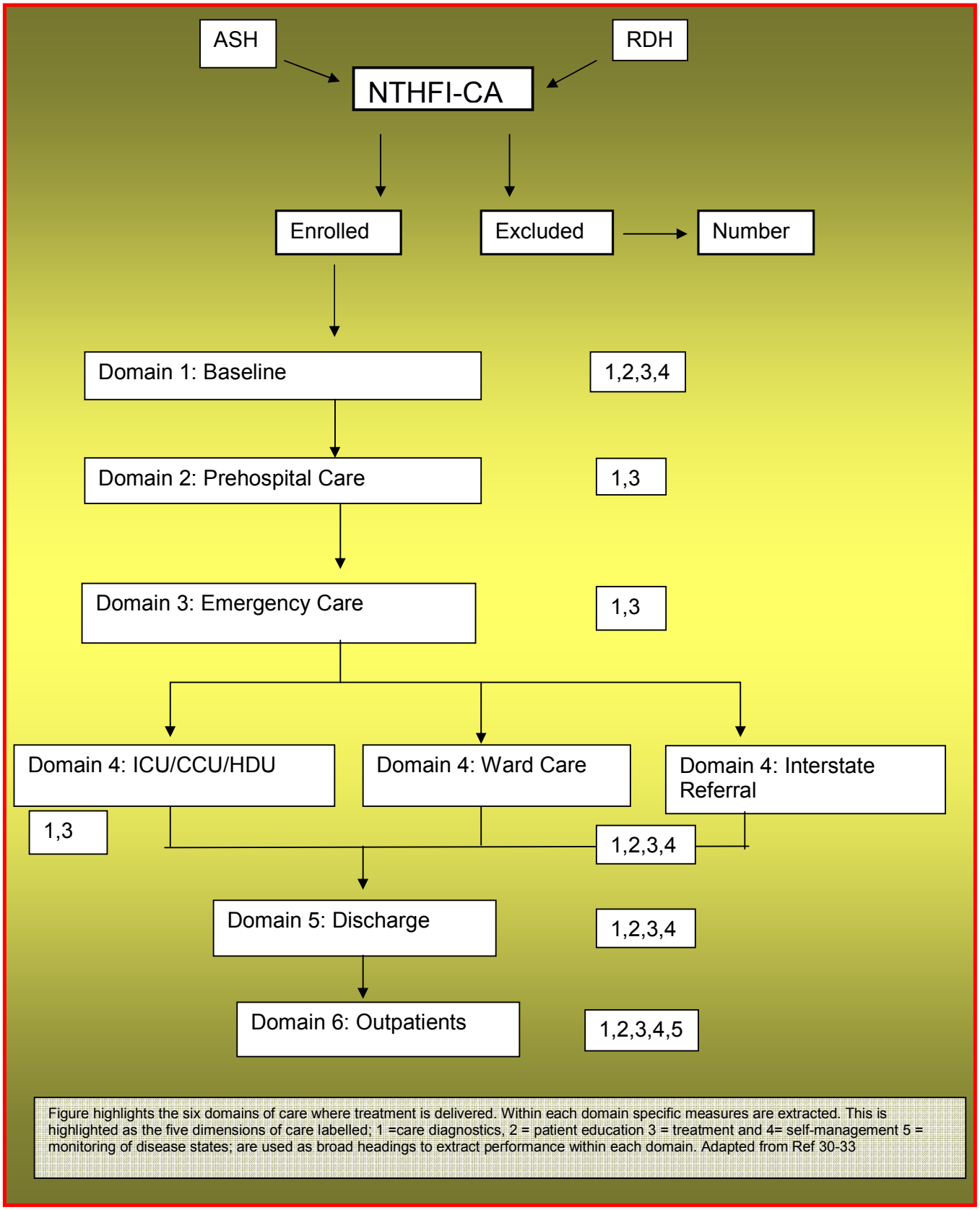


Figure highlights the six domains of care where treatment is delivered. Within each domain specific measures are extracted. This is highlighted as the five dimensions of care labelled; 1 =care diagnostics, 2 = patient education 3 = treatment and 4= self-management 5 = monitoring of disease states; are used as broad headings to extract performance within each domain. Adapted from Ref 30-33

Box 4 Performance measures within each treatment dimensions divided into mild and moderate or greater ADHF (Ref 31,32)

Domain	1 χ	2 δ	3	4	5	6 ε
CHF						
Mild	1.1-14 2 3.1-13 4	1.1-7 3.1-7	1.1-13 3.1-8	1.1-14 2 3.1-8 4	1.1-7,14 2 3.1-7 4	1.1-14 2 3.1-13 4 5
Mod +	1.1-14 2 3.1-13 4	1.1-7 3.1-.8	1.1-14 3.1-10	1.1-14 3.1-13	1.1-7,14 2 3.1-7 4	1.1-14 2 3.1-13 4 5

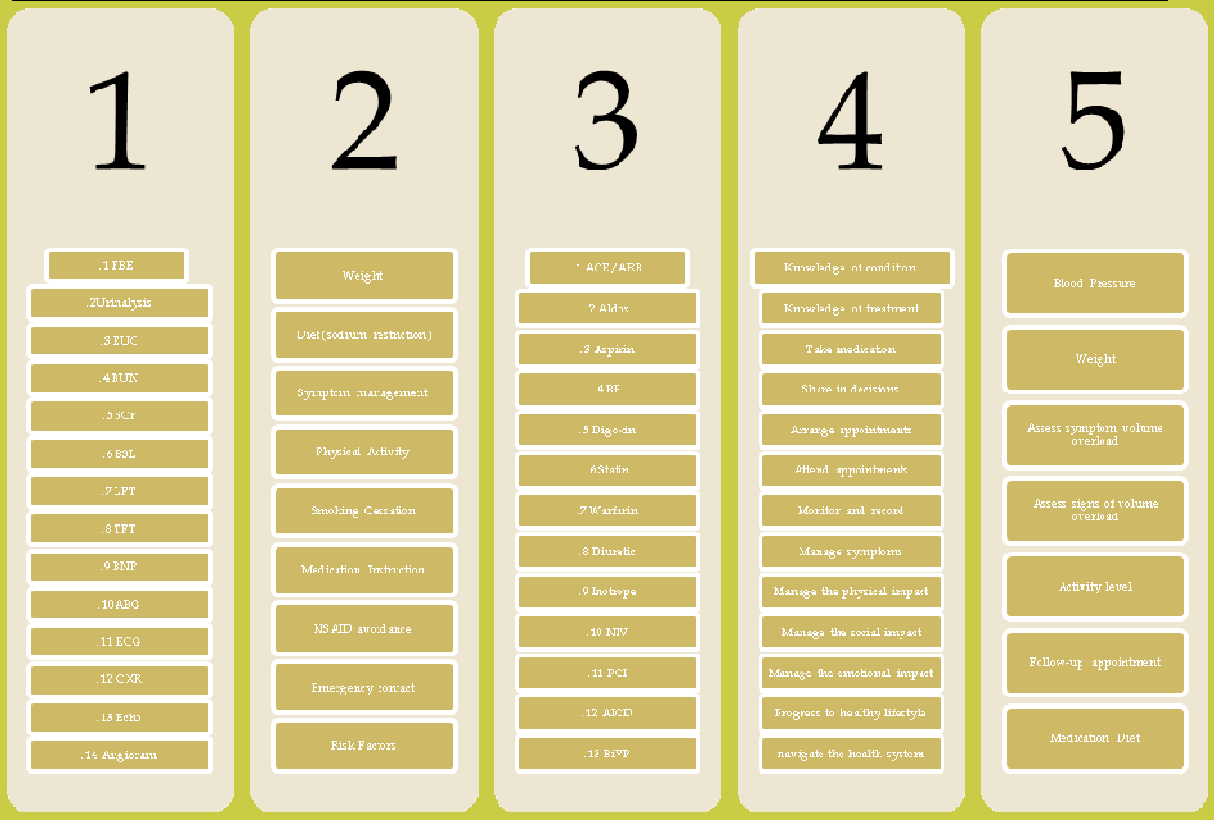


Figure provides a detailed description of the performance measures assessed within each of the five dimensions of care. The measures omitted are described in more detail in the discussion section of this paper.
χBNP – Appendix 2; ICER unknown
δPoint of care devices variably available in different communities
εIndigenous patients remote PPM monitoring
Dimension 1: Standard blood tests, electrolytes, renal function, liver function, arterial blood gas
Dimension 3:ACE/ARB/Aldos – Renin Angiotensin system blockers – ACE-i titration see appendix 4; ββ -beta blockers - titration see Appendix 5. AICD – automated implanted cardioverter defibrillator; BiVP – biventricular pacemaker; NIV – non invasive ventilation; PCI – percutaneous coronary intervention
Dimension 4: There are 14 essential action points; only principles are listed in this box (see appendix 6)
Dimension 5: 7 vital action points for monitoring of heart failure

Figure highlights the six domains of care where treatment is delivered. Within each domain specific measures are extracted. This is highlighted as the five dimensions of care labelled; 1 =care diagnostics, 2 = patient education 3 = treatment and 4= self-management 5 = monitoring of disease states; are used as broad headings to extract performance within each domain. Adapted from Ref 30-33

APPENDIX A DEFINITIONS FOR Acute CHF and Stages (Ref 40)
(BNP based definitions not used, as it is not available in the NT for acute use)

Clinical Presentation	Incidence*	Signs and Symptoms	Characteristics
1. Elevated systolic blood pressure	>50%	Usually develop abruptly	Predominantly pulmonary (radiographic/clinical) rather than systemic congestion due to rapid fluid redistribution from systemic to pulmonary circulation; many patients have preserved EF
2. Normal systolic blood pressure	>40%	Develop gradually (days or weeks) and are associated with significant systemic congestion	Despite high ventricular filling pressure, radiographic pulmonary congestion may be minimal because of pulmonary vasculature/lymphatics adaptation due to chronic elevated left atrial pressures
3. Low systolic blood pressure (90 mm Hg)	<8%	Usually have a low cardiac output with signs of organ hypoperfusion	Many of those patients have advanced or end-stage HF
4. Cardiogenic shock	<1%	Rapid onset	Primarily complicating acute MI, fulminant myocarditis
5. Pulmonary edema	<3%	Rapid or gradual onset	Clinical: severe dyspnea, tachypnea, tachycardia, and hypoxemia, requiring immediate airway intervention Radiographic: present in up to 80% of patients; often not associated with clinical pulmonary edema
6. “Flash” pulmonary edema	?	Abrupt onset	Precipitated by severe systemic hypertension. Uncorrected, respiratory failure and death ensue. Patients are easily treated with vasodilators and diuretics. After blood pressure normalization and reinstitution of routine medications, patients can be discharged within 24 h
7. Isolated right HF	?	Rapid or gradual onset	Not well characterized; there are no epidemiological data (eg, acute cor pulmonale, right ventricular infarct)
8. Acute coronary syndromes (25% of patients have signs/ symptoms of HF)	?	Rapid or gradual onset	Many such patients may have signs and symptoms of HF that resolve after initial therapy or resolution of ischemia
9. Post–cardiac surgery HF	?	Rapid or gradual onset	Occurring in patients with or without previous ventricular dysfunction, often related to worsening diastolic function and volume overload immediately after surgery.

STAGE	Description
A	Patients at high risk for HF but without structural heart disease or symptoms of HF (e.g., patients with hypertension, atherosclerotic disease, diabetes, obesity, and metabolic syndrome or patients using cardiotoxins or with a family history of cardiomyopathy). Such patients have no identified structural or functional abnormalities of the pericardium, myocardium, or cardiac valves and have never shown signs or symptoms of HF.
B	Patients who have developed structural heart disease that is strongly associated with the development of HF (e.g., previous myocardial infarction, LV remodeling including LVH and low EF, or asymptomatic valvular disease) but without signs or symptoms of HF.
C	Patients with structural disease who have current or prior symptoms of HF (e.g., known structural heart disease and shortness of breath and fatigue, reduced exercise tolerance).
D	Patients with refractory HF requiring specialized interventions (e.g., marked symptoms of HF at rest despite maximal medical therapy—those who are recurrently hospitalized or cannot be safely discharged from the hospital without specialized interventions).

APPENDIX B Attributes of Performance Indicators (Ref 32)

Choosing Performance Measures	
Selection Factors	**Considerations**
Adherence to the potential performance measure results in meaningful improvements in clinically important outcomes	Evidence-based trials, strong clinical practice guideline recommendations for (Class I, Level of Evidence: A) or against (Class III, Level of Evidence: A) the measure
Broad sampling from multiple domains associated with the process of medical care (see Figure 1)	Measures should be distributed across the domains of diagnosis, patient education, treatment, patient self-management, and serial monitoring of success of treatment
Attributes of Selected Measures	
Measure Characteristics	**Relevant Attributes**
Useful in improving patient outcomes	Interpretable Actionable
Measure design	Denominator precisely defined Numerator precisely defined Established types of validity • Face • Content • Construct Established reliability
Measure implementation	Feasibility • Reasonable effort • Reasonable cost • Reasonable time period for collection
Overall assessment by Performance Measures Writing Group	Overall assessment of measure by explicit, predefined criteria for inclusion in measurement set

Adapted from Normand SL et al.[2]

APPENDIX C Choosing Performance Indicators (Ref 32)

Choosing Performance Measures	
Selection Factors	**New Considerations**
Confidence that adherence to a potential performance measure would result in meaningful improvements in clinically important outcomes	The methodology and logic by which a performance measure was selected, with a clear description of anticipated benefits on meaningful clinical outcomes, should be disclosed by the writing committee.
Costs of measure	Explicit demonstration that application of the performance measure to patients is associated with an acceptable ICER. An estimate of the societal burden of more complete adherence to the performance measure.
Outcomes measures	The outcomes to be considered must be clinically relevant, including mortality, irreversible morbidity, and health status (symptoms, function, and quality of life), and surrogate outcomes should be avoided. Previously published recommendations for publicly reported outcomes should be followed.[22] Risk adjustment, with carefully selected clinical variables and explicit consideration of demographic characteristics, must be available to render observations interpretable. Where possible the population should represent a disease state rather than a procedure applied to a subset of that population.
Measure Characteristics	**New Considerations**
Use of exceptions	Exclusions of patients from the denominator of a performance measure are reasonable and should be broadly grouped into • medical • patient • system-based reasons for why the patient was not eligible
No. of measures	To minimize the number of measures, efforts at creating a national consensus, involving all stakeholders, on measures to be used for a specified period of time for accountability, pay for performance, and quality-improvement efforts should be developed. Although performance measure writing committees should create a full complement of measures for a disease, the NQF should select only a subset of these for use at any particular time. The subset should include measures from multiple dimensions of care to facilitate a more complete assessment of quality. Measures should be retired when new evidence questions the association of those measures with clinically meaningful outcomes or performance is so high that there is little room for future improvement. Retired measures should be considered for reassessment in future years.
Feasibility of data collection	Data collection should occur prospectively through routine transactions of medical care because retrospective collection of data is not sustainable. EMR companies need to create and support export of data using standardized formats so that a greater number of providers can participate in national quality-assessment programs. Measures need to be developed in a way that recognizes the longitudinal patient care experience and creates "windows" for capturing performance that are practical and clinically interpretable.
Composite measures	The psychometric properties of these measures, including reliability, accuracy, and predictive validity, should be demonstrated. The purpose, intended audience, and scope of a composite measure should be explicitly stated. The individual measures used to create a composite measure should be evidence-based and reliable. The methodology used for weighting and combining individual measures into a composite performance measure should be transparent and empirically tested. Composite performance measure reporting by providers should include a measure of the degree of uncertainty surrounding composite estimates.
Attribution	Accountability is an important opportunity to improve practice. It is essential that those held accountable have the processes of care being assessed under their locus of control. More methodological work is needed for promotion of the concept of shared accountability for evaluating transitions in care.

EMR indicates electronic medical record; ICER, incremental cost-effectiveness ratio; and NQF, National Quality Forum.

Appendix D Heart Failure Disease Management Scoring System (Ref 33)

Table. Heart Failure Disease Management Scoring Instrument

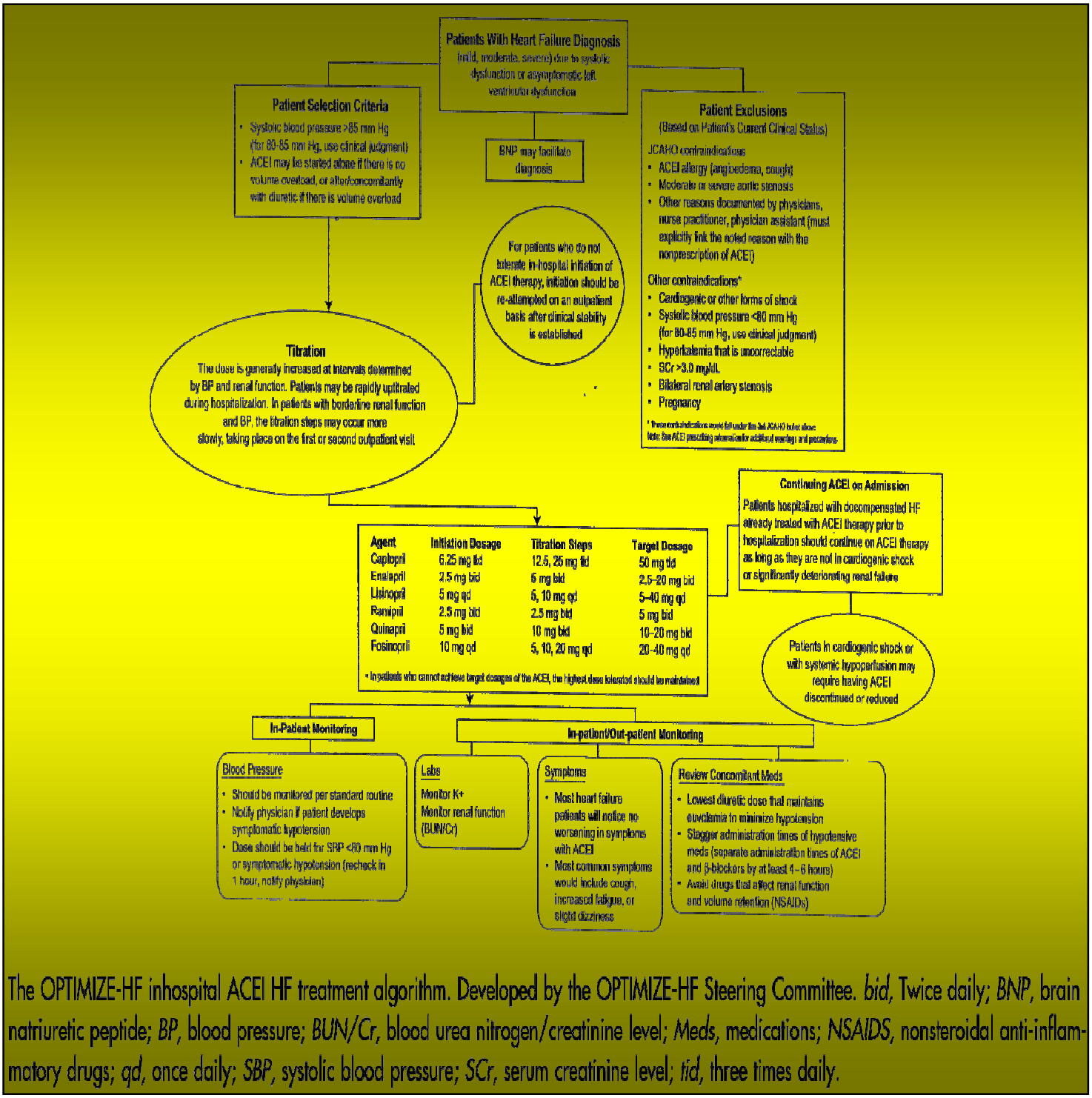
Intervention Category	Points to be Assigned	Comment/Rationale
Recipient	1=Provider alone 2=Patient alone 3=Patient with some inclusion of caregiver 4=Patient with a caregiver who is central to the intervention	Most interventions focus on the patient; yet, coding scheme recognizes that some interventions are aimed at improving provider behavior (eg, system intervention aimed at evidence-based care). Most points are given to interventions that focus on the patient but also include caregivers because an engaged family member act as 2nd set of eyes and memory support, which can deter hospitalization. Thus: 2 points assigned if focus was on patient alone; 3 points if there is some inclusion of the caregiver, 4 points if inclusion of the caregiver was a major component of the intervention.
Intervention content		
Education and counseling aimed at supporting self-care	0=No mention of education 1=Focus solely on importance of treatment adherence 2=Focus on treatment adherence including some creative methods of improving adherence 3=Focus on surveillance but no mention of actions to be taken in response to symptoms (eg, no flexible diuretic management) 4=Emphasis on surveillance, management, and evaluation of symptoms in addition to treatment adherence	Interventions are derived from Krumholz et al,[5] with point allocations assigned to reflect current literature that suggests these interventions are not comparable in efficacy. Individualized patient education and counseling is essential because patients must be engaged in the process of self-care and helped to learn how to make decision about managing their HF. However, true self-care is more than treatment adherence.
Medication management	0=No mention of medication regimen 1=Some mention of medications (eg, importance of medication compliance) but not an active part of the intervention. No attempt to intervene with provider to get patients on an evidence-based medication regimen 2=Evidence-based medication regimen advocated but no follow-up with patient or provider to monitor the suggestion 3=Medication regimen monitored, attempt made to get the patient on evidence-based medications, with follow-up monitoring done with patient or provider	Patients on optimal, evidence-based therapies are significantly less likely to have acute exacerbations and hospital admissions.
Social support Peer support	0=No mention of a peer support intervention 1=Peer support mentioned but not integral to intervention 2=Peer support integral component of intervention	Peer support interventions not used commonly but when used they appear to improve perceived support rather than self-care. Support has been conceptualized as a moderator of the relationship between intervention and outcome.
Surveillance by provider: Remote monitoring	0=No use of remote monitoring or telehealth 1=Remote monitoring is used in conjunction with other interventions that form the main intervention used 2=Telehealth is essential component of intervention	Remote monitoring is distinguished from other methods of communication. Video monitoring may become a common method of communication. For now, remote monitoring is conceptualized as method of engaging patients in process of learning self-care by active engagement.
Delivery personnel	1=Single generalist provider (eg, physician, nurse, pharmacist)	Generalist: Provider specifically noted to not have training in heart failure.
	2=Single HF expert provider (eg, physician, nurse, pharmacist)	Multidisciplinary interventions: Multidisciplinary team involved with all or most patients.
	3=Multidisciplinary intervention	Integrated/choreographed multidisciplinary intervention: Provided by multiple disciplines in collaboration; provided in an HF clinic with policies/protocols specified for HF care.
	4=Multidisciplinary intervention provided in an integrated, choreographed manner	Optimal mix of program delivery personnel is not known, thus assigned points are hypothesized in this study.
Method of communication	1=Mechanized via internet or telephone 2=Person-to-person by telephone 3=Face-to-face, individual, or in a group 4=Combined: Face-to-face at least once alone or in a group with individual telephone calls in between meetings	Most interventions involve combined individual approach with telephone/face-to-face contact. Points should be assigned based on predominant method of communication The method of communication varies widely within individual HF disease management programs, making it difficult to judge how the method influences outcomes. Thus, assigned points are hypothesized in this study.

Table. *Continued*

	Points to be Assigned	Comment/Rationale
Intensity and complexity		Some literature suggests that more intense, complex, and lengthy interventions are associated with better outcomes, though simple interventions have also been effective. Two categories were created to capture this item: Duration and complexity.
Duration	1=≤1 mo 2=≤3 mo 3=≤6 mo 4=>6 mo	
Complexity	1=Low: single contact with little or no follow-up 2=Moderate: >1 but <4 and/or infrequent contact or contacts of short duration 3=High: multiple contacts of significant duration	Complexity is judged on frequency of content and duration of visits/calls. Assigned points are hypothesized in this study.
Environment	1=Hospital: Inpatient only 2=Clinic/outpatient setting 3=Home-based 4=Combination of settings	Krumholz et al[5] note that it is not yet clear which environmental factors are associated with success. Thus assigned points are hypothesized in this study. Many interventions are provided in a more than 1 setting, and scoring endeavors to capture these combinations.

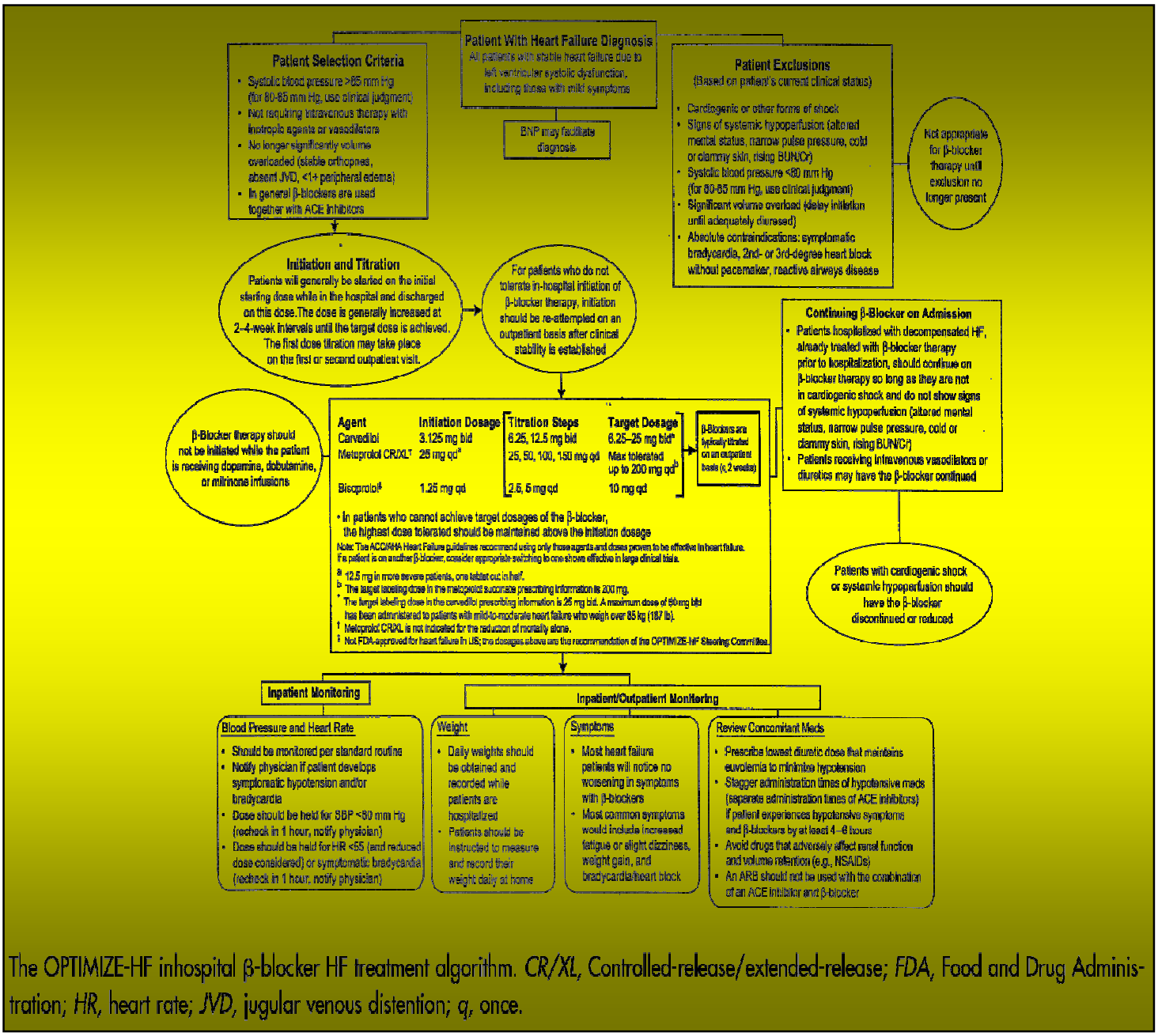
Note: All available sources describing the intervention should be used to ascribe scores.
Reprinted from Krumholz et al,[5] with permission from Lippincott Williams & Wilkins. Copyright 2006, American Heart Association.

Appendix E Model of ACE-I Titration in OPTIMIZE-HF (Ref 34)



The OPTIMIZE-HF inhospital ACEI HF treatment algorithm. Developed by the OPTIMIZE-HF Steering Committee. *bid*, Twice daily; *BNP*, brain natriuretic peptide; *BP*, blood pressure; *BUN/Cr*, blood urea nitrogen/creatinine level; *Meds*, medications; *NSAIDS*, nonsteroidal anti-inflammatory drugs; *qd*, once daily; *SBP*, systolic blood pressure; *SCr*, serum creatinine level; *tid*, three times daily.

Appendix F Model of Beta- Blocker Titration in OPTIMIZE-HF (Ref 34)



The OPTIMIZE-HF inhospital β-blocker HF treatment algorithm. *CR/XL*, Controlled-release/extended-release; *FDA*, Food and Drug Administration; *HR*, heart rate; *JVD*, jugular venous distention; *q*, once.

APPENDIX H: The Flinders ProgramTM for Chronic Condition Management Information Paper - SUMMARY (Ref 45)

The Principles of Self-management	**Aim of the Flinders ProgramTM**	**Assessment Tools Goals**
1. Have knowledge of their condition 2. Follow a treatment plan (care plan) agreed with their health professionals 3. Actively share in decision making with health professionals 4. Monitor and manage signs and symptoms of their condition 5. Manage the impact of the condition on their physical, emotional and social life 6. Adopt lifestyles that promote health 7. Have confidence, access and the ability to use support services.	1. Improves the partnership between the client and health professional(s) 2. Collaboratively identifies problems and therefore better (i.e. more successfully) targets interventions 3. Is a motivational process for the client and leads to sustained behaviour change 4. Allows measurement over time and tracks change 5. Has a predictive ability, i.e. improvements in self-management behaviour as measured by the PIH scale, relate to improved health outcomes.	1. Partners in Health Scale 2. Cue and Response interview 3. Problems and Goals Assessment • Identification of Issues • Formation of an individualised Care Plan • Monitoring and reviewing

PIH	**C&R**	**Problem and Goals (P&G) Assessment**
• Knowledge of condition • Knowledge of treatment • Ability to take medication • Ability to share in decisions • Ability to arrange appointments • Ability to attend appointments • Understanding of monitoring and recording • Ability to monitor and record • Understanding of symptom management • Ability to manage symptoms • Ability to manage the physical impact • Ability to manage the social impact • Ability to manage the emotional impact • Progress towards a healthy lifestyle • Ability to know and navigate the health system	• The C&R process uses a series of open-ended questions or cues to explore the patient's responses to the PIH Scale in more depth. E.g. • **Knowledge of Treatment** - What can you tell me about your treatment? - What other treatment options including alternative therapies do you know about? - What does your family/carer understand about your treatment? • **Sharing in Decisions** - Does your doctor/health worker listen to you? - How involved to you feel in making decisions about your health? • **Healthy Lifestyle** - What are you doing to stay healthy as possible? - What things to you do that could make your health	- The Problems and Goals assessment is another tool that can be used as an adjunct to the PIH and C&R process or as a stand-alone assessment. **Notes:** The health worker may well see one of these issues as the main or biggest problem for the client. The client may see the same thing as their biggest problem but they may see something else as having a far greater impact. For example, the clinician might think that the way the client uses their medication is the biggest problem, however the client may think their biggest problem is the demands the family places on them, perhaps they are caring for grandchildren everyday and have little time for themselves. As well as defining the problem from the client's perspective, this assessment also clearly identifies a goal or goals that the client can work towards

BMJ open

Northern Territory Heart Failure Initiative – Clinical Audit (NTHFI – CA)
A Prospective Database on the Quality of Care and Outcomes for Acute Decompensated Heart Failure Admission in the Northern Territory - Study Design and Rationale

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Northern **T**erritory **H**eart **F**ailure **I**nitiative **– C**linical **A**udit **(NTHFI – CA)**

A Prospective Database on the Quality of Care and Outcomes for Acute Decompensated Heart Failure Admission in the Northern Territory - Study Design and Rationale

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Abstract

Introduction: Congestive Heart failure is a significant cause of morbidity and mortality in Australia. Accurate data for the Northern Territory and Indigenous Australians is not presently available. The economic burden of this chronic cardiovascular disease is felt by all funding bodies and it still remains unclear what impact current measures have on preventing the ongoing disease burden and how much of this filters down to more remote areas. Clear differentials also exist in rural areas including a larger Indigenous community, greater disease burden, differing aetiologies for heart failure as well as service and infrastructure discrepancies. It is becoming increasingly clear that urban solutions will not affect regional outcomes. To understand regional issues relevant to heart failure management, an understanding of the key performance indicators in that setting is critical.

Methods and Analysis: The **N**orthern **T**erritory **H**eart **F**ailure **I**nitiative **– C**linical **A**udit **(NTHFI-CA)**, is a prospective registry of acute heart failure admissions over a 12 month period across the 2 main Northern Territory tertiary hospitals. The study collects information across 6 domains and 5 dimensions of health care. The study aims to set in place an evidenced and reproducible audit system for heart failure and inform the developing heart failure disease management programme. The outcomes it is hoped will assist the development of solutions to narrow the outcomes divide between remote and urban Australia and between Indigenous and Non-Indigenous Australians, should they exist. A combination of descriptive statistics and mixed effects modelling will be used to analyse data.

Ethics and Dissemination: This study has been approved by respective ethics committees of both the admitting institutions. All participants will be provided a written informed consent which will be completed prior to enrolment in the study. The study results will be disseminated through local and international health conferences and peer reviewed manuscripts.

Introduction

The congestive heart failure (CHF) syndrome is the leading cause for admissions and is in the top three causes for mortality in the Western World. It is associated with significant morbidity, impacts on individual's quality of life and through the necessity of frequent medical and allied health interventions, prescription of pharmacological agents and recurrent hospitalizations, is a source of stress on health resources. Guidelines based care improves outcomes but challenges exist in implementation. Neglecting this resource intensive investment leads to poor outcomes and so the cycle perpetuates. CHF is speculated, as no accurate prospective data is available, to be higher in the Northern Territory (NT) and among Indigenous Australians. The recent **C**entral **A**ustralian **S**econdary **P**revention of **A**cute Coronary Syndromes (**CASPA**) study highlighted a significant burden of CHF, greater among the Indigenous communities[1], confirming earlier studies of under representation nationally[2]. These works have highlighted several key indicators relevant for the NT[1-15]:

1) There is a *high burden* of CHF that cannot be explained by *traditional risk factors* alone. Among the Indigenous population, given that social factors influence the risk of CHF the excess in mortality is most likely to be multifactorial in origin, and have its foundations in the economic, social, physiological, psychological and educational disadvantages[1].
2) There appears a greater burden of CHF related to rheumatic and *non-ischemic aetiology*, which is reversible and has a better prognosis when treatment is delivered or preventive measures enforced [2-6,14].
3) There appears a greater burden of CHF with *co-morbidities* among Indigenous clients, which requires greater resources to deliver comprehensive care[2].
4) There are significant *barriers and differentials* in *access* to appropriate, acceptable and evidence based medical care and preventative measures for Indigenous and remote clients. New delivery methods are important as CHF can largely be delivered as community based care[14-25].
5) There is significant *delay in presentation* and receipt of acute care during periods of decompensation and for geographical and other reasons delay of definitive therapies or procedures[25,26].
6) There is poor *uptake* of post-discharge services such as cardiac rehabilitation and at present unknown demographics that will assist implementation of remote allied health or technological based solutions[3,14].
7) Unique *geography* - the NT consists of a vast area with 2 major public hospitals in Alice Springs and Darwin servicing 230,000 clients, approximately 70% live within the urban proximity. Specialist services reside at the tertiary hospitals with satellite district hospitals in several smaller townships supporting a small number of visiting specialists. Service planning must take this into account[3,15].
8) *External validity* - adherence to guidelines early in hospital admission can improve outcomes, however not all groups meet trial conditions in remote areas nor are trial conditions for dosing strategies reproducible [5]. A consensus on therapeutics strategies is needed.

Lack of accurate prospective data for the listed points makes it difficult to accurately develop a tailored, yet comprehensive HF program. Developing tools to gather evidence require adhering to standards for validity and reproducibility, which are also lacking. This study is focused on understanding the current evidence base for quantifying health care systems and informing the design of diagnostic and management clinical audits that would form the backbone for the direction of CHF disease management systems within a NT context. We thus propose to study the quality and outcomes of care for patients admitted with acute decompensated heart failure (ADHF). We aim to develop key clinical and process of care performance indicators (KPI) and translate these findings for improved service delivery if and where deficiencies are highlighted. This paper describes the rationale for the NTHFI-CA design.

Methods

Aims and Scientific Hypotheses

The NTHFI-CA survey was designed with 4 major objectives: Firstly to develop validated and reproducible key clinical and process of care indicators (KPI) for the comprehensive measurement of quality of care and outcomes for clients admitted with ADHF. In this we aim to measure for the clients, the proportion meeting standardised clinical outcomes, process outcomes and defined targets of secondary prevention and compare by age, ethnicity, sex and place of usual residence. For the health system, identify failures of the health care system in relation to timely acute care and to the provision of secondary CHF care, particularly for indigenous and remote clients; Secondly to develop a system of data collection and reporting, that can be used for ongoing quality assessment and improvement across the care continuum; Thirdly, the results of the first two objectives are hoped will help tailor a pilot intervention study similar to the ongoing nurse led intervention developed around the CASPA-ACS study findings; Fourthly to accumulate sufficient epidemiology and implementation focused information to steer future action in the provision, monitoring and development of guidelines based quality CHF care for rural, urban, Indigenous and Non Indigenous clients. We hypothesize that patients presenting with ADHF are expected to have: a disproportionate representation of Indigenous clients with advanced systolic impairment; excess of alcohol, ischemic or rheumatic aetiology; greater co-morbidities in diabetes, hypertension, lipid abnormalities and/or renal insufficiency, and with other non cardiac co-morbidities; delayed presentations for Indigenous and remote clients; We hypothesize that treatment for Indigenous and remote clients: are likely suboptimal for the stage of HF; have fewer clinical interventions and support compared to their urban counterparts; are less likely to receive novel therapeutic options or enrolled in multicentre trials; are more likely to have their HF managed without regular cardiology specialist input.

Projected Outcomes

We anticipate several outcomes from this work: Firstly, *identification* of the points of weaknesses in the hospital and community health centre systems that impact on both urban, rural, indigenous and non-indigenous clients and hopefully lead to the development of focused service improvement models across this care continuum; Secondly, to *link* with a number of collaborative research projects assessing barriers to care for indigenous clients suffering with heart diseases; Thirdly, lead to the development of *ongoing and sustainable* quality improvement practices and monitoring within hospital and PHC services across the region; Fourthly, help develop, trial and implement *standardised* medical discharge summaries and care plans during hospital stay and following discharge; Fifthly, explore the potential *contribution* of poor systems of care to the high level of illness faced by Indigenous people; and Finally, assessment of the potential barriers that may exist for primary and secondary *prevention* for CHF. These goals should initially drive improved service delivery and subsequently provide a baseline for evaluating ongoing service outcomes on which to base future acute and preventive program development and inform the development of alternative models of secondary prevention for NT clients with CHF.

Protocol

The project is made up of two specific stages. *Stage 1* is the collaborative development of suitable KPI covering both process and outcome measures across the continuum of care and *Stage 2,* involves 2 phases, is the

development of appropriate, feasible data collection tools and their subsequent measurement in both hospital and primary health care settings.

The Development of Appropriate Clinical Indicators (Stage 1)

We conducted an extensive literature review with key words “heart failure or acute heart failure or chronic heart failure or congestive heart failure”; and “database or study design or study rationale or registry”; and “Data Collection/ or Quality Indicators, Health Care/ or Management Audit/ or performance indicators.mp or Healthcare Disparities/Quality Assurance, Health Care/ or Quality of Health Care/ or Quality Indicators, Health Care/ or quality of care indicators.mp or "Outcome and Process Assessment (Health Care)"/ or process of care.mp”. Published and established existing KPI for measuring the quality and outcomes of care for patients experiencing ADHF were collated[7-13, 30-41]. The CASPA study KPI was used as a template. Within 6 domains and 5 dimensions of care KPI were added or rested on this template using the ACC/AHA attributes of performance measures[32]. Addition or removal required consensus of the principal investigator and one co-investigator. Uniform agreement by all co-investigators was required for accepting the final measures (Box 1 and 2). Acute Coronary Syndrome, (as an aetiology for ischemic cardiomyopathies or aggravator of existing cardiomyopathies) and KPI that were deemed not to add any additional benefit on what was already known from CASPA were also rested.

Study Design and Registry (Stage 2)

The NTHFI-CA registry is a prospective observational cohort study designed to examine the performance of health systems in relation to the acute management and secondary prevention of ADHF in patients admitted to two regional hospitals in the NT, Royal Darwin Hospital (RDH) and Alice Springs Hospital ASH) commencing September 2013 and followed for 12 months ending September 2015. Performance will be measured against currently available evidence based guidelines for the treatment and secondary prevention CHF[4,7-10-12,30,34-39]. Data collected will enter NTHFI-CA study registry located at Baker IDI Heart and Diabetes Institute, Alice Springs. All documentation relating to study participants will be treated in accordance with National Statement of Ethical Conduct in Human Research[42].

Eligibility Criteria: Patients admitted to either hospital with the diagnosis of HF (ICD-10CM I42.0-I42.8,143.0, 150.0-150.9) will be eligible for the prospective case note audit. The subjects will also be drawn from in-patients who develop acute symptoms whilst in hospital for other reasons. Further assessment will also involve the generation of lists ICD CM I00-I02, I05-I09, I10-I15, I20-I28, I30-I41, I44-I49, I70-I89, I95-I99 (complicated with acute heart failure) for cross checking of initial coding and recording of outcome variables. Subjects will be considered eligible if the review of medical records demonstrates that they in fact have suffered an ADHF based on ACC/AHA and National Health Data Dictionary standardised definitions

Exclusion Criteria: Patients will be excluded if they die within 24 hours of admission or do not usually reside within either region or whom no follow-up data can be obtained, however, these clients will still provide baseline incidence data. Cases that do not fulfil the case definition of ADHF on review of the notes will also be excluded, and recorded but will not form baseline data.

Population/Recruitment of Subjects: A dedicated research assistant will recruit consecutive patients who present acutely to either hospital or transferred from remote indigenous communities from the emergency clinical screen and medical admission lists for. Of these, clients who are Aboriginal, are non-Aboriginal, have a documented

urban residence and reside in remote communities with will be followed. The subjects will also be drawn from in-patients who develop acute symptoms whilst in hospital for other reasons. Flyers will be posted in emergency, wards, intensive care and a brief presentation made to the medical and nursing staff at relevant units. Referrals from hospital staff in this form will be a secondary recruitment strategy. For retrospective audit lists of individuals will be generated through hospital separation and CCU admissions data for the years 2011 and 2012. The approved research assistant in each site will perform this. An independent physician will review uncertain cases.

Data Collection and Storage: Data will be collected on a standardised case note extraction form developed during phase one of the project. Information will be accessed through multiple sources including hospital records, primary health care clinic records, specialist databases, and record systems maintained by visiting district medical officers. The period of interest for data collection will be 0-12 months after discharge following documented ADHF. Data definitions will be standardised and widely accepted case and outcome definitions as outlined in the ACC Clinical Data Standards[10-12,32-38]. All cases that demonstrate ambiguity in data definitions or outcome data will initially be discussed with site investigator, if ambiguity persists, the principal investigator and a locally convened panel of the research team will review, and consensus sought.

Measurement of Performance: Phase 1 involves prospectively auditing admitted clients hospital records. Phase 2 involves further assessment of performance and will involve the auditing of client records held at remote community health centres, urban primary health care centres, specialists' records, hospital records, outpatient and cardiac rehabilitation files. Files are coded and stored by 3 health providers, NT Department of Health and Community Services (DHCS - ASH/RDH), Primary health care records (PHC) and NT Cardiac Services Pty Ltd. NT DHCS hospital separation data, hospital records coding and storage of data follows a nationwide format. PHC records will also be accessed to complete the secondary prevention and follow-up components of the audit and is subject to variability. NT Cardiac, main provider of cardiac diagnostics and outpatient care, databases and coronary intervention information systems holds a range of clinical and cardiac investigation/intervention (angiography, coronary stenting, echocardiography, stress testing) information. This information will be used to complete the data collection sheet for each patient file. Denominator and numerator values for KPI will be based on standardised values from ACC/AHA guidelines, local laboratory specification for biochemical tests and Australian accrediting bodies for invasive and non-invasive investigations. Overall performance will be compared to the National benchmark for CHF outcomes. As this is subject to change the broad principals will include CSANZ, Heart Foundation and locally published studies that involve a public tertiary HF referral centre from any of the 6 states in Australia. We will also seek the opinion of several local leading HF clinicians should there be issues standardising these benchmarks.

Participant Follow-up: Clients will be followed up to determine subsequent hospitalization, major medical events and interventions. Similar ICD codes for acute CHF will be used for screening Information at 1, 6 and 12 months. Data extraction will include a combination of case notes review, medical databases, contact with PHC and clients directly. Consent for this will be obtained during the initial recruitment.

End Points: The main indicators we are measuring cover a range of domains across the spectrum of care for people with ADHF. In brief variables include:

- Baseline
  - Demographics: Age, sex, usual place of residence, ethnicity;
  - Background: Past medical history of CHF and treatments, known risk factors and co morbidities;
  - Symptom onset: Time, nature, location, first point of contact with PHC, delay times to care.

- Pre-Hospital Management: Appropriate medical/paramedical assessment, provision of pre-hospital nitrates, diuretics, ventilation and analgesia;
- Emergency Department: presentation, delays, biochemistry, investigations (CXR, ECG, echocardiography), therapeutics (assisted ventilation, IV nitrates or diuretics); risk stratification.
- Admission Details: clinical examination, investigations, management, complications during admission, performance of phase I rehabilitation;
- Discharge: Discharge diagnosis, discharge status, medication regime, referral to phase II cardiac rehabilitation, discharge planning and referral to primary health care provider;
- Outpatients:
  - Cardiac rehabilitation: Attendance and completion of cardiac rehabilitation.
  - Secondary Prevention: risk factor modification, care plan, cardiac education received, measurement of and achievements of specified target goals for HF and prevention of risk factors related to aetiology (eg CVD i.e. smoking cessation, lipid control, BP control), complications.
  - Self- Management.
  - Depression - PHQ9.
  - Outcomes: re-admission, major cardiovascular and non-cardiovascular events, mortality.
  - IT and Telecommunications: availability, access and type of mobile phone and Internet platforms.

Special Ethical Consideration and Adverse Events: Cultural and religious issues surrounding confidentiality and storage of human tissue are of significant importance for Indigenous clients. The NT is also host to a diverse multiethnic population. We have thus chosen not to store samples for future use. We have sought specific support from key Indigenous Community groups, NT-DHCS, Cardiac Services, Remote and Primary Health Services, Independent Health Services and Indigenous Health Services, in advance. As primarily a hospital and clinic file audit, this proposal does not directly broach the issues of reciprocity, respect, equality, responsibility, survival and protection, which are critical in Indigenous research, confirmation of which was obtained through the ethics submission. We do not anticipate any other adverse events. *We have received full ethics approval to conduct the study by Central Australia and Top End Human Research Committees.*

Training and Standardization

This project requires access to data housed and maintained by NT DHCS and NT Cardiac Services. Hospital Separation Data, Hospital Records and PHC Records will be sought from NT DHCS and will be arranged through PI's in Darwin. In the event that PHC records are housed within independent services (non-DHCS clinics) appropriate consultation will be undertaken as requested by the independent services themselves. Formalised consent processes as directed by Independent services will be followed. If they wish to perform the audit themselves, as a training and quality assurance process, appropriate training and support will be provided by the research team. All staff recording information will be briefed by training staff from the CASPA study and undergo education in variability or data recording, ambiguous data and differing case records, ICD-10 classification, ACC/AHA guidelines for KPI[28] and NHMRC good clinical practice as the minimum requirement. Addressing ambiguity has been discussed under data collection and storage.

Expected Sample Size

On the basis of generated hospital separation and CCU statistics, 2009, for ASH of 113 and RDH of 450 patients, the sample population will be approximately 150 patients with ADHF at ASH and 500 matched at RDH (27) in the

time period 2009. Of the ASH separations, 99 (88%) are identified as being indigenous. The matched (ethnicity and gender) RDH sample extrapolates to 180 (40%), Aboriginal clients in phase II. As data will be collected on three separate occasions for each patient, a robust dataset is expected to identify any significant associations between predictors and patient outcomes. Findings from this investigation will also inform the development of more testable hypotheses in future studies and appropriate sample sizes.

Statistical considerations

All generated data will be entered into and analysed with SPSS v 11.5. Initial data analysis will be conducted to assess for data quality including allowable ranges, data structure and errors. Descriptive statistics for baseline participant characteristics, diagnostics and therapeutics within highlighted domains will be calculated and presented as means (standard deviation), interquartile range (IQR) for continuous data and count (percent) for categorical data. Univariate between group analyses will be performed using t tests for continuous variables, and χ^2 tests of association for categorical variables. For study outcome measures, a Type 1 error rate o alpha=0.05 will be used to test for statistical significance. A generalised mixed-effects model approach will be used in the analysis of repeated measures for continuous and categorical outcomes. Mixed-effects models take into account the inter-individual differences in intra-individual change with repeated responses and use all the available data on each subject. Mixed models are also unaffected by randomly missing data and therefore do not require imputation methods[46]. The model building strategy will include fitting nested models by sequentially adding blocks of predictor variables: socio-demographics, co-morbid disorders and factors related to health service interventions. Interaction terms that are considered to be potentially important from a clinical perspective will be tested and remain in final models if significant. Predicted estimates of outcomes at each time point will be calculated using fitted models of the data in order to examine patterns of individual change. To interpret effect sizes and precision for categorical outcomes, odds ratios and confidence intervals will be calculated.

Discussion

The NTHFI-CA represents one of a few opportunities offered for longitudinal studies designed to extract data that informs service development. Information gathered has to be relevant for current and future needs. It is difficult to determine service factors beyond 5 yearly intervals. To compensate for this, there have been measures taken to set infrastructure and standardise protocols to facilitate episodic updates in information as well as ensuring reproducibility of study design and implementation. With the actual study design a series of steps were taken. The first step was establishing basic principles for defining the disease (Box 1, Appendix A). The second step involved standardising principles for attributes in KPI i.e. care dimensions (Box 2.1, Appendix B & C) and the study care domains to be tested, in this case 6 (Box 2.2). The third step involved addressing the broad NT health goals and research conduct in Indigenous population to steer implementation within 5 key priorities (Box 2.3). The fourth step is design of disease management systems in the NT context from the available evidence (Box 2.4, Appendix D). The specific details are explored.

The ACC/AHA has released several position statements to standardise the process of developing, assessing, implementing performance measures and disease management systems[30-33]. From this consensus driven platform, we identified the target disease, population and explored standardised measures that inform the observation for the required time period. The NTHFI-CA is defined for all stages and causes of CHF, for NT resident population who receive care within 6 domains of treatment. This broad definition partly relates to uncertainties on actual CHF demographics, and as the yearly admission are unlikely to exceed 500, will not lead to significant difficulties in enrolment. To determine the performance measures we again explored the position statement. The authors rated 27 potential measures on 13 dimensions using a 5-point Likert scales[32]. If a KPI received full committee support with a score of at least 3, it was advanced. The process concluded with 7 inpatient and 12 outpatients' measures. These KPI informed five dimensions of care encompassing; diagnostics, patient education (including prognosis and aetiology), treatment, and self-management (for inpatient and outpatient) and monitoring of disease status (for outpatients only)[32]. This statement did not however focus on outcomes as the design was shaped to assist physicians improve care. We have included outcomes, as this is the strongest indicator for funding for vulnerable groups beyond the conventional block funding models. To determine the final KPI several additional points were considered:

I. *Existing Studies:* Several recent databases stand as land mark achievements in HF epidemiology and have confirmed clinical understanding of evidence base and positive outcomes[10-12,36,38,44]. Interestingly Krumholz etal[31] pointed out a disparity between what is conventionally accepted evidence and its generalisabilty. This is particularly so for the NT where there are significant non-traditional factors that impact on the delivery of evidence based care and affect outcomes. While it would be unreasonable to propose reconducting large CHF studies to incorporate an increasingly diverse group of patients we have come to realise that at the heart of these matters is developing an intrinsic understanding of the underlying regional demographic differences and service delivery dynamics to be able to formulate informed decisions in implementing the necessary measures, be they simple or more complex. Developing the necessary KPI in these settings is a challenge as there is a divide between perceived optimal care and, realistic and deliverable care that is in fact optimal for the region. From this it was evident that some measures needed to be rested (e.g. treatment optimization) and others added (e.g. the dimension of technology).

II. *NT Experience:* The CASPA study was ground breaking in the sense that it allowed for the first time exploration of ACS/cardiovascular KPI in Central Australia. The list was formulated from an extensive search of available national and international clinical guidelines, national health priority area indicators and reports and with reference to National Health Performance Committee guidelines and further augmented by performance measures used in published quality improvement projects. 3 priorities - process of care, target achievement and outcome indicators for the treatment and prevention were generated. This list underwent scrutiny by 60 key stakeholders, key external content experts and the research team through mailed questionnaires and a workshop convened in Alice Springs. Each stakeholder was asked to grade each potential indicator according to a number of criteria: Strength of evidence; feasibility of measurement; plausibility of effects from quality improvement; impact on outcomes; and an assessment of the overall utility of the measure. Results were collated and analysed for each indicator (overall grading) and for each of the five criteria across each indicator. Indicators that were graded as high priority, frequently recorded, very plausible and will have a large impact or better were included in the final list (average score on grading scale ≥ 4.0). Indicators that demonstrate an across criteria grade of less than 4, but was assessed by key stakeholders as a high or essential priority within the overall (utility) rating, were scrutinised by the project team and included as decided by consensus. Data specifications were then developed according to internationally standardised definitions. Subsequent data collection tools were developed and piloted in a number of hospital and PHC records (n=20) and implemented. The spill over knowledge assisted greatly in the NTHFI-CA design.

Combining this local and international experience, with the standardized ACC position[32], a conceptual framework KPI reflecting 6 critical domains for treatment delivery and 5 principal dimensions of care evolved (Box 2). All these well established performance measures were individually scrutinised and included or rested. Level of evidence was the predominant scrutinizing theme in the second phase. The less validated 'local knowledge' and NT health priorities were additional considerations. Study investigators made the decisions on these. Several less well established indicators were included through recent understanding and development of self-management and IT based solutions[15]. In direct contrast to intervention themed databases[35,36] focus on specifics in the treatment dimension was given a lower priority (see appendix E, F). Box 4 describes this in greater detail.

Further rationale for specific KPI inclusion or exclusion are as follows: Domain 1: Demographics are at the heart of this study. Validated KPI derived from CASPA were used to extract race, culture, language and support networks; further expansion was made in the dimension of HF aetiology with emphasis on ischemic, hypertensive as well as rheumatic and alcohol induced causes. Data on tertiary referral centres were collected, as there were 2 main cardiac surgical referral hospitals. Decision referral patterns vary with the treating physician practices as well as waiting list and urgency. It is established that decisions on percutaneous or surgical revascularisation and valvular restoration or replacement differs at these sites on physician, group consensus and expertise at the respective sites. Details on primary care physician, pharmacy, residence and principal next of kin were deemed important as local and ethnicity were deemed factors in service uptake and delivery. Furthermore access to primary care could determine - admission, readmission burden and early measures to prevent deterioration; Domain 2 -5: A comprehensive past medical history of all systems were included to establish the overall need for chronic medical service needs and factors preventing use or uptake of HF pharmacology, cardiac rehabilitation or referral for invasive management. Biochemistry details were included to establish pattern of establishing HF aetiology and outpatient risk for adverse events. Methods for estimating eGFR was obtained as much recent work raises validity of estimated measures with illness and demographics, which subsequently alter prescribing

practices and outcomes[12,13,45]. KPI for depression were expanded as a high burden was noted in CASPA, this also being a significant factor in many dimensions of self-care and compliance. In hospital, discharge and outpatient indicators were designed to reflect potential blocks to maximising proven pharmacological prescription and access to cardiac rehabilitation, at the core of these were reasons for non-prescription or sub-therapeutic prescription. The actual specifics on medication titration across all domains were rested. It is noted that care and resources are needed to titrate many variables in CHF care, for e.g. ββ and ACE-I (Appendix E &F). This information can be extrapolated from frequency of contact with medical practitioner and central pharmacy prescription slips. Appropriate early therapeutics - to prevent further heart muscle damage, good symptom relief and minimising iatrogenic adverse effects such as renal dysfunction and electrolyte derangements is within the control of the health systems and builds client confidence, and is considered vital, this dimension was included. Domain 6: Overall we felt, in the community, that the greatest value in the performance measures related to 2 critical aspects - impacts on the overall health system (strain and morale) and contributors to poor outcomes (client and non-client). Post hospital access to services and blocks to referrals (non client) and self-management (client) are factors related to efficiency, planning and client education. Investment in these dimensions would not increase strain on resources, with potential benefit.

Data collection instrument was via Case Report Forms (CRF) designed for a combination of retrospective and prospective audit from combination of several studies CASPA and WHICH. The Baker IDI, Flinders University, and SAHMRI have extensive track record in electronic CRF. This was greatly beneficial and reduced challenges faced for stage 2. At present much research work is conducted through the Menzies School of Health Research. As part of this initiative we have began the process of developing dedicated office to conduct studies across the cardiac and renal axis. Part of this also involved staff training in good clinical practice and transfer of knowledge form partners to stand as an independent entity*.

Indigenous health in the NT requires special focus. Australia has seen the first Indigenous premier in 2013 and a measured but controversial statement of removing the Indigenous ministerial portfolio was “there are numerous ministers for many areas and one for all Indigenous affairs”. Current sentiments that move away from race based programs are encouraged but with caution. We clarify that out approach does not target any specific communities but is based on needs. It is unfortunate that disadvantaged communities are also marginalised in large studies partly for language, cultural and perceived compliance issues. In this case the Indigenous community represent a significant group in Australian society who have despairingly worse outcomes. The desire to preserve ones traditional culture in an ever modernising world proves huge challenges for these communities and health systems. Poor understanding could lead to stereotyping that could brand some behaviour as recalcitrant, adding to the vicious circle. Respecting these beliefs and tailoring care in lieu of these factors we were able to advance the CASPA study. This was done through acknowledgement as several sensitive areas in the ethics application; *Equality* - The overarching aims of the research project is based within a framework driven by questions of equality in the provision of health care across the continuum for all patients regardless of ethnicity, gender or age, and one based on need as demonstrated by clinical determinants; *Survival and Protection* - We also recognise that chronic disease research and epidemiology has tended to contribute to deficit approaches to individual pathology; that is disease is due to bad behaviour. Less focus has been afforded the potential successes and

* *Information on our partners and expertise can be found on the web or via corresponding author.*

failures in health systems, as contributors to differential outcomes for populations based on ethnicity; *Respect* - "We feel that information generated within this project and the processes developed have the potential to contribute to community directed health service redevelopment and quality improvement activities; *Reciprocity* - We feel that this work may identify failures in health systems and therefore identify obligations that are being unmet by systems themselves; *Responsibility* - Re-framing the gaze of health inequality, from individual focused deficits to system failures stands as the key principle on which this extensive work is based, and is a direct effort at ensuring that exploring health inequalities does not undermine and harm Indigenous individuals and communities. These principles may play great importance to future research practices in these areas.

Interim analysis will be conducted at the 6-month mark. It is anticipated at this point lessons learnt and spill over knowledge from the ongoing CASPA-ACS intervention study may direct minor modifications to the existing CRF. One such area is increasing the KPI in domains 1, 2 and 6 to better understand the barriers to accessing primary care. CHF, an ambulatory case sensitive condition, can largely be managed in the community with the application of appropriate and timely preventive care and early disease management. The issues that remain unclear at this point are the adequacy and the barriers for accessing such care in each of the remote communities. Of interest, Ansari etal noted that a lack of timely and effective care had an impact on admission rates in rural Victoria particularly among lower socio-economic groups[47,48]. A similar understanding in the NT could impact on how we allocate resources in the future.

Measuring performance is not an end in its own right and clinical indicators and their measurement alone are not sufficient to change behaviour in service provision and quality improvement. They must be supplemented with key educational activities (e.g. provision of continuous and sustained feedback of results to all levels of service provision), processes to sustain continuous monitoring and assessment and to inform policy development on a local and regional level. Clearly defined dissemination processes and involvement of Aboriginal Health Workers, hospital and community based nurses, allied health professionals and clinicians are essential if practice is to change. Engaging non-governmental (NGO) service providers, data coders, quality improvement staff, NGO's (NHF NT Division, Healthy Living NT), Division of General Practice/Primary Health Care and consumer representatives in the development phase of the project so as to ensure alignment between proposed indicators and local needs. The dissemination of key findings through key advisory/research institutions will also increase the awareness nationally/globally and build foundations for future competitive research funding. Finally, we also have been in negotiations for the broader applicability of the findings of and tools utilised within this project with the Australian Collaborative Project (which seeks to measure PHC performance). This stands as a critical method of project outcome dissemination.

Limitations:

Conducting clinical studies in the NT is in itself a limitation; firstly, the realization of non-traditional risks factors, which impact on management; secondly, as there are few benchmarks as comparators; and finally shortfalls in research funding and infrastructure. While no system has the perfect mix of resource input to match service needs to answer this question, for this region, there will be components within many aspects of the study that is hypothesis generating, compared to the mainstream. Nonetheless following the accepted consensus and providing enough information to allow reproducibility is accepted as a positive means for overcoming this limitation. Examples of this were resting KPI that collate in depth information on medication dosing as per RCT's

and large HF databases[31-39]. This study will not address whether clinical trial prescribing practices are achieved, instead we are keen to determine if there is a system in place to facilitate this, which will be answered. The infrastructure is also in place for the next step to determine if this can occur. We note that RCT level outcomes relate to achieving prescribing practices in the trials. As examples Appendix E/F, highlight differences in just 2 medications. *As noted, ββ titration is ideally done at 2 weekly intervals and may not need biochemistry, while ACE-I can be done at 3-7 day intervals and usually require assessment of basic biochemistry. Addition of aldosterone blockers and other agents are further complexities*. We are hopeful that relevant information on this will help steer the next phase, an intervention audit. This study relied on lessons from ACS study conducted greater than 5 years ago. Unanticipated changes that cannot be standardized could act as confounders, which will only be revealed in time; e.g. is potential drop off rate during follow-up. In the standardization of design – we did not use 5 point Likert scale, as the number of NT consultants was only 4. In addition the CHF task force position was comprehensive[32]. Finally, clinical practice guidelines are well established, as Krumholtz stated "guidelines are written in a spirit of suggesting diagnostic or therapeutic interventions for patients in most circumstances. Accordingly, significant judgment by clinicians is required to adapt these guidelines to the care of individual patients to ensure accountability in these judgments an evidenced based process is important". The standardizing of clinical judgment and interpretation of guidelines remains contentious and may be more noticeable with fewer cardiologists. As such we intentionally left the criteria for KPI reference broad. This will be narrowed, as lessons are learnt and early data are analyzed. This should aid more focused and detailed assessments in the future.

** We have not provided treatment pathways for AICD/CRT/ other pharmacotherapies. These are available from several optimizing databases (34,35,37).*

Conclusion

Achieving optimal care in the remote setting is no different from urban settings. The ability to provide a continuum of care from presentation to post discharge requires activation of proven KPI at each level of care. The significant differences in remote care revolve around the interaction of service infrastructure, personnel, disease burden and cultural sensitivities. As such the outcomes limiting factors are variable and require exploration. The potential gains of these findings in implementing early and later secondary prevention of CHF and its sequelae are undisputed. In addition, little information exists on the provision and outcomes for CHF initiatives for indigenous populations, which are a significant client base in the remote setting. Even less is known about the post-discharge care. The extent to which care is sub-optimal and the acute and long-term HF management among Aboriginal clients could be contributing to the large and growing cardiovascular mortality differentials seen between Aboriginal and non-Aboriginal clients. Thus the development of meaningful, sustainable public health, clinical and continuous quality improvement policy in the provision of CHF care in the NT requires urgent attention, and must be used to drive the development of better service delivery at both the individual and health system levels. It is anticipated that this work will highlight key areas of disparity and inform the implementation of an intervention study.

Abbreviations

ACE-I – Angiotension Converting Enzyme Inhibitor

ACS – Acute coronary syndrome

ADHF – Acute decompensated heart failure

ASH – Alice Springs Hospital

ββ - Beta Blockers

CASPA – Central Australian Secondary Prevention of Acute Coronary Syndrome Study

CASPA-HF – Central Australian Secondary Prevention of Acute Heart Failure Study

CHF – Congestive Heart Failure

CRF – Case Report Form

CVD – Cardiovascular Disease

DHCS – Department of Health and Community Services

ICD – International Classification of Diseases

KPI – Key Performance Indicators

NGO – Non-Governmental Organisations

NHF – National Heart Foundation

NT – Northern Territory

NTHFI – CA - **N**orthern **T**erritory **H**eart **F**ailure **I**nitiative **– C**linical **A**udit

PHC – Primary Health Care

RCT – Randomized Controlled Trial

RDH – Royal Darwin Hospital

Contributorship Statement

All authorship credit are be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. The current authors meet conditions 1, 2, and 3.

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BOX 1: ICD 10 Diseases of the circulatory system. Primary screening includes codes I42, I43 and I50. Secondary screening involved ADHF during index admission with highlighted codes

ICD-10-CM Code	Primary classification (I42,I43,I50) Description
I42.0	Dilated Cardomyopathy
I42.1	Chronic systolic (congestive) heart failure
I42.2	Acute on chronic systolic (congestive) heart failure
I42.3	Unspecified diastolic (congestive) heart failure
I42.4	Acute diastolic (congestive) heart failure
I42.5	Chronic diastolic (congestive) heart failure
I42.6	Acute on chronic diastolic (congestive) heart failure
I42.8	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I43	Cardiomyopathy is diseases classified elsewhere
I50.1	Left heart failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.9	Heart failure, unspecified

ICD-10-CM Code	Secondary Acute Heart Failure with these Admission Codes Description
I00-I02	Acute Rheumatic Fever
I05-I09	Chronic Rheumatic Heart Disease
I10-I15	Hypertensive Heart Diseases
I20-I25	Ischemic Heart Diseases
I26-I28	Pulmonary Heart Disease and Diseases of Pulmonary Circulation
I30-I32	Pericardial Diseases
I33-	Endocardial Diseases
I34-I39	Nonrheumatic valve disorders
I40-I41	Myocarditis
I44-I45	Conduction system Disorders
I46	Cardiac Arrest
I47-I49	Tachyarrhytmias
I70-I79	Diseases of arteries, arterioles and capillaries
I80-I89	Diseases of veins, lymphatic vessels and lymph nodes, not elsewhere classified
I95-I99	Other and unspecified disorders of the circulatory system

BOX 2 Design of the NTHFI-CA involved 4 steps: 1 – using a set of standardised principles (blue box) and their attributes (green box) we formulated outlines for each performance attribute (final column). CASPA shaped many aspects of design and implementation attributes; 2 - four basic factors shaped the broad study outline; 3 – highlights the ethical considerations for studies in the NT; 4 – broad disease management goals for which performance measures hope to inform. (Ref 30-33)

Principles and Recommendations From the AHA's Expert Panel on Disease Management
1. The main goal of disease management should be to improve the quality of care and patient outcomes.
2. Scientifically derived, peer-reviewed guidelines should be the basis of all disease management programs. These guidelines should be evidence based and consensus driven.
3. Disease management programs should help increase adherence to treatment plans based on the best available evidence.
4. Disease management programs should include consensus-driven performance measures.
5. All disease management efforts must include ongoing and scientifically based evaluations, including clinical outcomes.
6. Disease management programs should exist within an integrated and comprehensive system of care in which the patient–provider relationship is central.
7. To ensure optimal patient outcomes, disease management programs should address the complexities of medical comorbidities.
8. Disease management programs should be developed for all populations and should particularly address members of underserved or vulnerable populations.
9. Organizations involved in disease management should scrupulously address potential conflicts of interest.

1

ACC/AHA Attributes for Satisfactory Performance Measures (Appendix A/B)		NTHFI-CA
Useful in improving patient outcomes	1. Evidence-based 2. Interpretable 3. Actionable	Ref 28-30
Measure design	1. Denominator precisely defined	Inclusion/Exclusion
	2. Numerator precisely defined	Yes CHF
	3. Validity - Face validity - Content validity - Construct validity	CASPA
	4. Reliability	CASPA
Measure implementation	1. Feasibility - Reasonable effort - Reasonable cost - Reasonable time period for collection	CASPA
Overall assessment		Pending

Box 3 Trial Protocol and Study Pathways

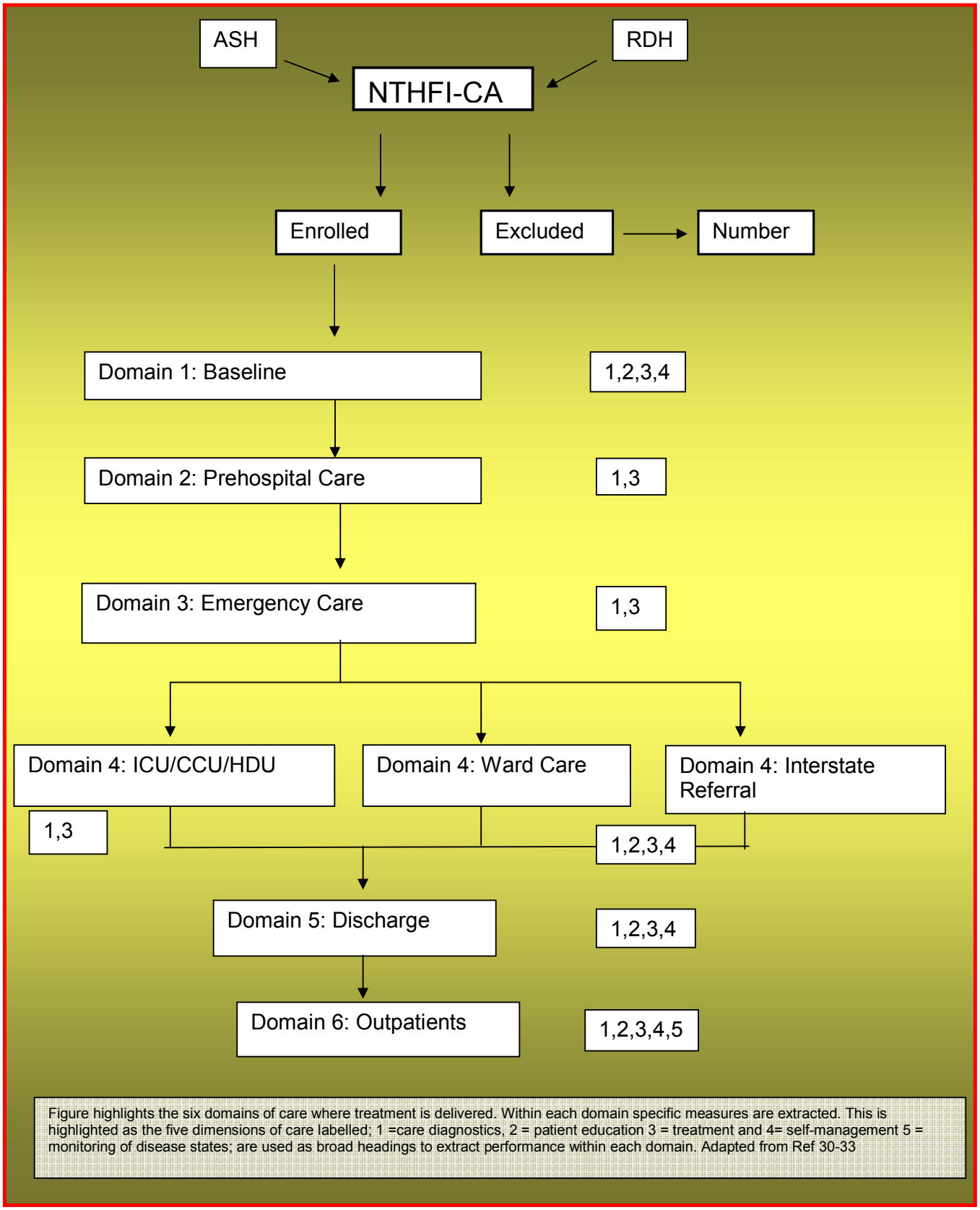

Figure highlights the six domains of care where treatment is delivered. Within each domain specific measures are extracted. This is highlighted as the five dimensions of care labelled; 1 =care diagnostics, 2 = patient education 3 = treatment and 4= self-management 5 = monitoring of disease states; are used as broad headings to extract performance within each domain. Adapted from Ref 30-33

Box 4 Performance measures within each treatment dimensions divided into mild and moderate or greater ADHF (Ref 31,32)

Domain	1 χ	2 δ	3	4	5	6 ε
CHF						
Mild	1.1-14 2 3.1-13 4	1.1-7 3.1-7	1.1-13 3.1-8	1.1-14 2 3.1-8 4	1.1-7,14 2 3.1-7 4	1.1-14 2 3.1-13 4 5
Mod +	1.1-14 2 3.1-13 4	1.1-7 3.1-.8	1.1-14 3.1-10	1.1-14 3.1-13	1.1-7,14 2 3.1-7 4	1.1-14 2 3.1-13 4 5

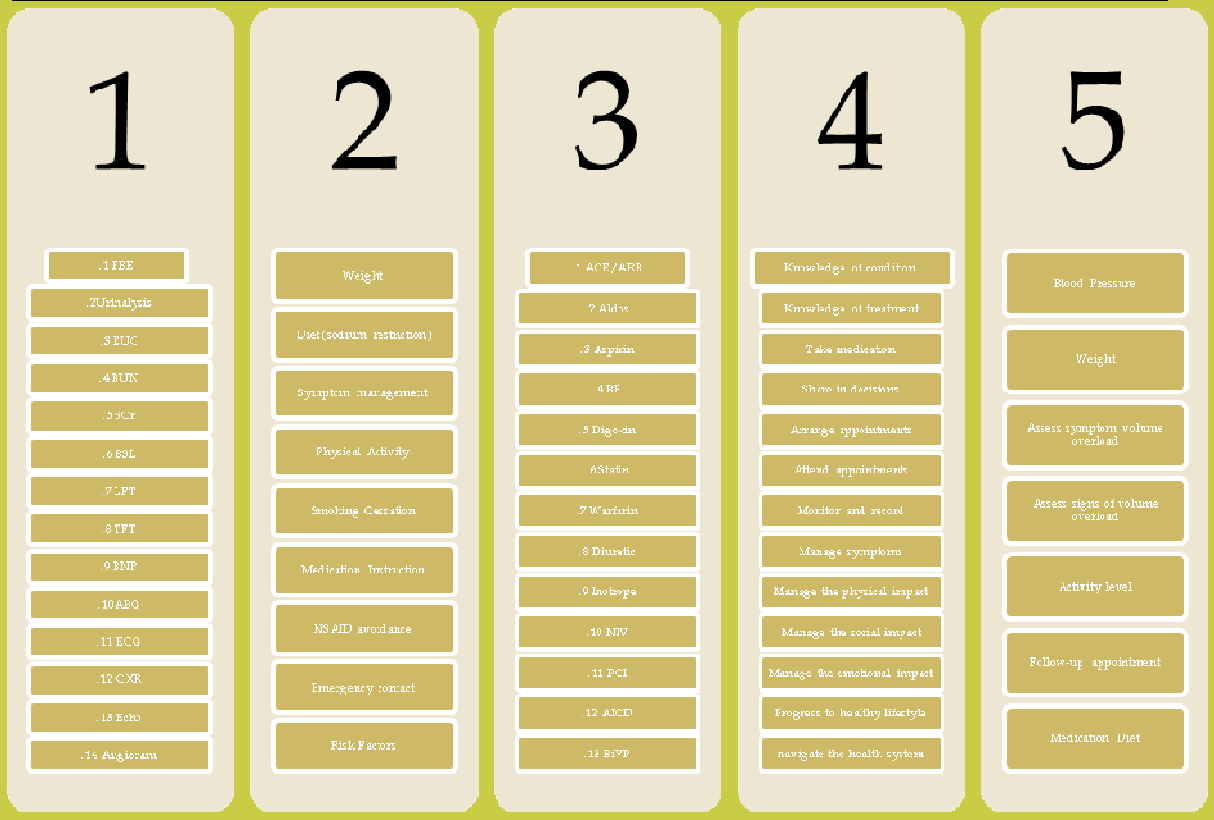

Figure provides a detailed description of the performance measures assessed within each of the five dimensions of care. The measures omitted are described in more detail in the discussion section of this paper.
χBNP – Appendix 2; ICER unknown
δPoint of care devices variably available in different communities
εIndigenous patients remote PPM monitoring
Dimension 1: Standard blood tests, electrolytes, renal function, liver function, arterial blood gas
Dimension 3:ACE/ARB/Aldos – Renin Angiotensin system blockers – ACE-i titration see appendix 4; ββ -beta blockers - titration see Appendix 5. AICD – automated implanted cardioverter defibrillator; BiVP – biventricular pacemaker; NIV – non invasive ventilation; PCI – percutaneous coronary intervention
Dimension 4: There are 14 essential action points; only principles are listed in this box (see appendix 6)
Dimension 5: 7 vital action points for monitoring of heart failure

Figure highlights the six domains of care where treatment is delivered. Within each domain specific measures are extracted. This is highlighted as the five dimensions of care labelled; 1 =care diagnostics, 2 = patient education 3 = treatment and 4= self-management 5 = monitoring of disease states; are used as broad headings to extract performance within each domain. Adapted from Ref 30-33

Northern **T**erritory **H**eart **F**ailure **I**nitiative **– C**linical **A**udit **(NTHFI – CA)**

A Prospective Database on the Quality of Care and Outcomes for Acute Decompensated Heart Failure Admission in the Northern Territory - Study Design and Rationale

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Abstract

Introduction: Congestive Heart failure is a significant cause of morbidity and mortality in Australia. Accurate data for the Northern Territory and Indigenous Australians is not presently available. The economic burden of this chronic cardiovascular disease is felt by all funding bodies and it still remains unclear what impact current measures have on preventing the ongoing disease burden and how much of this filters down to more remote areas. Clear differentials also exist in rural areas including a larger Indigenous community, greater disease burden, differing aetiologies for heart failure as well as service and infrastructure discrepancies. It is becoming increasingly clear that urban solutions will not affect regional outcomes. To understand regional issues relevant to heart failure management, an understanding of the key performance indicators in that setting is critical.

Methods and Analysis: The **N**orthern **T**erritory **H**eart **F**ailure **I**nitiative **– C**linical **A**udit **(NTHFI-CA)**, is a prospective registry of acute heart failure admissions over a 12 month period across the 2 main Northern Territory tertiary hospitals. The study collects information across 6 domains and 5 dimensions of health care. The study aims to set in place an evidenced and reproducible audit system for heart failure and inform the developing heart failure disease management programme. The outcomes it is hoped will assist the development of solutions to narrow the outcomes divide between remote and urban Australia and between Indigenous and Non-Indigenous Australians, should they exist. A combination of descriptive statistics and mixed effects modelling will be used to analyse data.

Ethics and Dissemination: This study has been approved by respective ethics committees of both the admitting institutions. All participants will be provided a written informed consent which will be completed prior to enrolment in the study. The study results will be disseminated through local and international health conferences and peer reviewed manuscripts.

Introduction

The congestive heart failure (CHF) syndrome is the leading cause for admissions and is in the top three causes for mortality in the Western World. It is associated with significant morbidity, impacts on individual's quality of life and through the necessity of frequent medical and allied health interventions, prescription of pharmacological agents and recurrent hospitalizations, is a source of stress on health resources. Guidelines based care improves outcomes but challenges exist in implementation. Neglecting this resource intensive investment leads to poor outcomes and so the cycle perpetuates. CHF is speculated, as no accurate prospective data is available, to be higher in the Northern Territory (NT) and among Indigenous Australians. The recent **C**entral **A**ustralian **S**econdary **P**revention of **A**cute Coronary Syndromes (**CASPA**) study highlighted a significant burden of CHF, greater among the Indigenous communities[1], confirming earlier studies of under representation nationally[2]. These works have highlighted several key indicators relevant for the NT[1-15]:

1) There is a *high burden* of CHF that cannot be explained by *traditional risk factors* alone. Among the Indigenous population, given that social factors influence the risk of CHF the excess in mortality is most likely to be multifactorial in origin, and have its foundations in the economic, social, physiological, psychological and educational disadvantages[1].
2) There appears a greater burden of CHF related to rheumatic and *non-ischemic aetiology*, which is reversible and has a better prognosis when treatment is delivered or preventive measures enforced [2-6,14].
3) There appears a greater burden of CHF with *co-morbidities* among Indigenous clients, which requires greater resources to deliver comprehensive care[2].
4) There are significant *barriers and differentials* in *access* to appropriate, acceptable and evidence based medical care and preventative measures for Indigenous and remote clients. New delivery methods are important as CHF can largely be delivered as community based care[14-25].
5) There is significant *delay in presentation* and receipt of acute care during periods of decompensation and for geographical and other reasons delay of definitive therapies or procedures[25,26].
6) There is poor *uptake* of post-discharge services such as cardiac rehabilitation and at present unknown demographics that will assist implementation of remote allied health or technological based solutions[3,14].
7) Unique *geography* - the NT consists of a vast area with 2 major public hospitals in Alice Springs and Darwin servicing 230,000 clients, approximately 70% live within the urban proximity. Specialist services reside at the tertiary hospitals with satellite district hospitals in several smaller townships supporting a small number of visiting specialists. Service planning must take this into account[3,15].
8) *External validity* - adherence to guidelines early in hospital admission can improve outcomes, however not all groups meet trial conditions in remote areas nor are trial conditions for dosing strategies reproducible [5]. A consensus on therapeutics strategies is needed.

Lack of accurate prospective data for the listed points makes it difficult to accurately develop a tailored, yet comprehensive HF program. Developing tools to gather evidence require adhering to standards for validity and reproducibility, which are also lacking. This study is focused on understanding the current evidence base for quantifying health care systems and informing the design of diagnostic and management clinical audits that would form the backbone for the direction of CHF disease management systems within a NT context. We thus propose to study the quality and outcomes of care for patients admitted with acute decompensated heart failure (ADHF). We aim to develop key clinical and process of care performance indicators (KPI) and translate these findings for improved service delivery if and where deficiencies are highlighted. This paper describes the rationale for the NTHFI-CA design.

Methods

Aims and Scientific Hypotheses

The NTHFI-CA survey was designed with 4 major objectives: Firstly to develop validated and reproducible key clinical and process of care indicators (KPI) for the comprehensive measurement of quality of care and outcomes for clients admitted with ADHF. In this we aim to measure for the clients, the proportion meeting standardised clinical outcomes, process outcomes and defined targets of secondary prevention and compare by age, ethnicity, sex and place of usual residence. For the health system, identify failures of the health care system in relation to timely acute care and to the provision of secondary CHF care, particularly for indigenous and remote clients; Secondly to develop a system of data collection and reporting, that can be used for ongoing quality assessment and improvement across the care continuum; Thirdly, the results of the first two objectives are hoped will help tailor a pilot intervention study similar to the ongoing nurse led intervention developed around the CASPA-ACS study findings; Fourthly to accumulate sufficient epidemiology and implementation focused information to steer future action in the provision, monitoring and development of guidelines based quality CHF care for rural, urban, Indigenous and Non Indigenous clients. We hypothesize that patients presenting with ADHF are expected to have: a disproportionate representation of Indigenous clients with advanced systolic impairment; excess of alcohol, ischemic or rheumatic aetiology; greater co-morbidities in diabetes, hypertension, lipid abnormalities and/or renal insufficiency, and with other non cardiac co-morbidities; delayed presentations for Indigenous and remote clients; We hypothesize that treatment for Indigenous and remote clients: are likely suboptimal for the stage of HF; have fewer clinical interventions and support compared to their urban counterparts; are less likely to receive novel therapeutic options or enrolled in multicentre trials; are more likely to have their HF managed without regular cardiology specialist input.

Projected Outcomes

We anticipate several outcomes from this work: Firstly, *identification* of the points of weaknesses in the hospital and community health centre systems that impact on both urban, rural, indigenous and non-indigenous clients and hopefully lead to the development of focused service improvement models across this care continuum; Secondly, to *link* with a number of collaborative research projects assessing barriers to care for indigenous clients suffering with heart diseases; Thirdly, lead to the development of *ongoing and sustainable* quality improvement practices and monitoring within hospital and PHC services across the region; Fourthly, help develop, trial and implement *standardised* medical discharge summaries and care plans during hospital stay and following discharge; Fifthly, explore the potential *contribution* of poor systems of care to the high level of illness faced by Indigenous people; and Finally, assessment of the potential barriers that may exist for primary and secondary *prevention* for CHF. These goals should initially drive improved service delivery and subsequently provide a baseline for evaluating ongoing service outcomes on which to base future acute and preventive program development and inform the development of alternative models of secondary prevention for NT clients with CHF.

Protocol

The project is made up of two specific stages. *Stage 1* is the collaborative development of suitable KPI covering both process and outcome measures across the continuum of care and *Stage 2,* involves 2 phases*,* is the

development of appropriate, feasible data collection tools and their subsequent measurement in both hospital and primary health care settings.

The Development of Appropriate Clinical Indicators (Stage 1)

We conducted an extensive literature review with key words “heart failure or acute heart failure or chronic heart failure or congestive heart failure”; and “database or study design or study rationale or registry”; and “Data Collection/ or Quality Indicators, Health Care/ or Management Audit/ or performance indicators.mp or Healthcare Disparities/Quality Assurance, Health Care/ or Quality of Health Care/ or Quality Indicators, Health Care/ or quality of care indicators.mp or "Outcome and Process Assessment (Health Care)"/ or process of care.mp”. Published and established existing KPI for measuring the quality and outcomes of care for patients experiencing ADHF were collated[7-13, 30-41]. The CASPA study KPI was used as a template. Within 6 domains and 5 dimensions of care KPI were added or rested on this template using the ACC/AHA attributes of performance measures[32]. Addition or removal required consensus of the principal investigator and one co-investigator. Uniform agreement by all co-investigators was required for accepting the final measures (Box 1 and 2). Acute Coronary Syndrome, (as an aetiology for ischemic cardiomyopathies or aggravator of existing cardiomyopathies) and KPI that were deemed not to add any additional benefit on what was already known from CASPA were also rested.

Study Design and Registry (Stage 2)

The NTHFI-CA registry is a prospective observational cohort study designed to examine the performance of health systems in relation to the acute management and secondary prevention of ADHF in patients admitted to two regional hospitals in the NT, Royal Darwin Hospital (RDH) and Alice Springs Hospital ASH) commencing September 2013 and followed for 12 months ending September 2015. Performance will be measured against currently available evidence based guidelines for the treatment and secondary prevention CHF[4,7-10-12,30,34-39]. Data collected will enter NTHFI-CA study registry located at Baker IDI Heart and Diabetes Institute, Alice Springs. All documentation relating to study participants will be treated in accordance with National Statement of Ethical Conduct in Human Research[42].

Eligibility Criteria: Patients admitted to either hospital with the diagnosis of HF (ICD-10CM I42.0-I42.8,143.0, 150.0-150.9) will be eligible for the prospective case note audit. The subjects will also be drawn from in-patients who develop acute symptoms whilst in hospital for other reasons. Further assessment will also involve the generation of lists ICD CM I00-I02, I05-I09, I10-I15, I20-I28, I30-I41, I44-I49, I70-I89, I95-I99 (complicated with acute heart failure) for cross checking of initial coding and recording of outcome variables. Subjects will be considered eligible if the review of medical records demonstrates that they in fact have suffered an ADHF based on ACC/AHA and National Health Data Dictionary standardised definitions

Exclusion Criteria: Patients will be excluded if they die within 24 hours of admission or do not usually reside within either region or whom no follow-up data can be obtained, however, these clients will still provide baseline incidence data. Cases that do not fulfil the case definition of ADHF on review of the notes will also be excluded, and recorded but will not form baseline data.

Population/Recruitment of Subjects: A dedicated research assistant will recruit consecutive patients who present acutely to either hospital or transferred from remote indigenous communities from the emergency clinical screen and medical admission lists for. Of these, clients who are Aboriginal, are non-Aboriginal, have a documented

urban residence and reside in remote communities with will be followed. The subjects will also be drawn from in-patients who develop acute symptoms whilst in hospital for other reasons. Flyers will be posted in emergency, wards, intensive care and a brief presentation made to the medical and nursing staff at relevant units. Referrals from hospital staff in this form will be a secondary recruitment strategy. For retrospective audit lists of individuals will be generated through hospital separation and CCU admissions data for the years 2011 and 2012. The approved research assistant in each site will perform this. An independent physician will review uncertain cases.

Data Collection and Storage: Data will be collected on a standardised case note extraction form developed during phase one of the project. Information will be accessed through multiple sources including hospital records, primary health care clinic records, specialist databases, and record systems maintained by visiting district medical officers. The period of interest for data collection will be 0-12 months after discharge following documented ADHF. Data definitions will be standardised and widely accepted case and outcome definitions as outlined in the ACC Clinical Data Standards[10-12,32-38]. All cases that demonstrate ambiguity in data definitions or outcome data will initially be discussed with site investigator, if ambiguity persists, the principal investigator and a locally convened panel of the research team will review, and consensus sought.

Measurement of Performance: Phase 1 involves prospectively auditing admitted clients hospital records. Phase 2 involves further assessment of performance and will involve the auditing of client records held at remote community health centres, urban primary health care centres, specialists' records, hospital records, outpatient and cardiac rehabilitation files. Files are coded and stored by 3 health providers, NT Department of Health and Community Services (DHCS - ASH/RDH), Primary health care records (PHC) and NT Cardiac Services Pty Ltd. NT DHCS hospital separation data, hospital records coding and storage of data follows a nationwide format. PHC records will also be accessed to complete the secondary prevention and follow-up components of the audit and is subject to variability. NT Cardiac, main provider of cardiac diagnostics and outpatient care, databases and coronary intervention information systems holds a range of clinical and cardiac investigation/intervention (angiography, coronary stenting, echocardiography, stress testing) information. This information will be used to complete the data collection sheet for each patient file. Denominator and numerator values for KPI will be based on standardised values from ACC/AHA guidelines, local laboratory specification for biochemical tests and Australian accrediting bodies for invasive and non-invasive investigations. Overall performance will be compared to the National benchmark for CHF outcomes. As this is subject to change the broad principals will include CSANZ, Heart Foundation and locally published studies that involve a public tertiary HF referral centre from any of the 6 states in Australia. We will also seek the opinion of several local leading HF clinicians should there be issues standardising these benchmarks.

Participant Follow-up: Clients will be followed up to determine subsequent hospitalization, major medical events and interventions. Similar ICD codes for acute CHF will be used for screening Information at 1, 6 and 12 months. Data extraction will include a combination of case notes review, medical databases, contact with PHC and clients directly. Consent for this will be obtained during the initial recruitment.

End Points: The main indicators we are measuring cover a range of domains across the spectrum of care for people with ADHF. In brief variables include:

- Baseline
  - Demographics: Age, sex, usual place of residence, ethnicity;
  - Background: Past medical history of CHF and treatments, known risk factors and co morbidities;
  - Symptom onset: Time, nature, location, first point of contact with PHC, delay times to care.

- Pre-Hospital Management: Appropriate medical/paramedical assessment, provision of pre-hospital nitrates, diuretics, ventilation and analgesia;
- Emergency Department: presentation, delays, biochemistry, investigations (CXR, ECG, echocardiography), therapeutics (assisted ventilation, IV nitrates or diuretics); risk stratification.
- Admission Details: clinical examination, investigations, management, complications during admission, performance of phase I rehabilitation;
- Discharge: Discharge diagnosis, discharge status, medication regime, referral to phase II cardiac rehabilitation, discharge planning and referral to primary health care provider;
- Outpatients:
  - Cardiac rehabilitation: Attendance and completion of cardiac rehabilitation.
  - Secondary Prevention: risk factor modification, care plan, cardiac education received, measurement of and achievements of specified target goals for HF and prevention of risk factors related to aetiology (eg CVD i.e. smoking cessation, lipid control, BP control), complications.
  - Self- Management.
  - Depression - PHQ9.
  - Outcomes: re-admission, major cardiovascular and non-cardiovascular events, mortality.
  - IT and Telecommunications: availability, access and type of mobile phone and Internet platforms.

Special Ethical Consideration and Adverse Events: Cultural and religious issues surrounding confidentiality and storage of human tissue are of significant importance for Indigenous clients. The NT is also host to a diverse multiethnic population. We have thus chosen not to store samples for future use. We have sought specific support from key Indigenous Community groups, NT-DHCS, Cardiac Services, Remote and Primary Health Services, Independent Health Services and Indigenous Health Services, in advance. As primarily a hospital and clinic file audit, this proposal does not directly broach the issues of reciprocity, respect, equality, responsibility, survival and protection, which are critical in Indigenous research, confirmation of which was obtained through the ethics submission. We do not anticipate any other adverse events. *We have received full ethics approval to conduct the study by Central Australia and Top End Human Research Committees.*

Training and Standardization

This project requires access to data housed and maintained by NT DHCS and NT Cardiac Services. Hospital Separation Data, Hospital Records and PHC Records will be sought from NT DHCS and will be arranged through PI's in Darwin. In the event that PHC records are housed within independent services (non-DHCS clinics) appropriate consultation will be undertaken as requested by the independent services themselves. Formalised consent processes as directed by Independent services will be followed. If they wish to perform the audit themselves, as a training and quality assurance process, appropriate training and support will be provided by the research team. All staff recording information will be briefed by training staff from the CASPA study and undergo education in variability or data recording, ambiguous data and differing case records, ICD-10 classification, ACC/AHA guidelines for KPI[28] and NHMRC good clinical practice as the minimum requirement. Addressing ambiguity has been discussed under data collection and storage.

Expected Sample Size

On the basis of generated hospital separation and CCU statistics, 2009, for ASH of 113 and RDH of 450 patients, the sample population will be approximately 150 patients with ADHF at ASH and 500 matched at RDH (27) in the

time period 2009. Of the ASH separations, 99 (88%) are identified as being indigenous. The matched (ethnicity and gender) RDH sample extrapolates to 180 (40%), Aboriginal clients in phase II. As data will be collected on three separate occasions for each patient, a robust dataset is expected to identify any significant associations between predictors and patient outcomes. Findings from this investigation will also inform the development of more testable hypotheses in future studies and appropriate sample sizes.

Statistical considerations

All generated data will be entered into and analysed with SPSS v 11.5. Initial data analysis will be conducted to assess for data quality including allowable ranges, data structure and errors. Descriptive statistics for baseline participant characteristics, diagnostics and therapeutics within highlighted domains will be calculated and presented as means (standard deviation), interquartile range (IQR) for continuous data and count (percent) for categorical data. Univariate between group analyses will be performed using t tests for continuous variables, and χ^2 tests of association for categorical variables. For study outcome measures, a Type 1 error rate o alpha=0.05 will be used to test for statistical significance. A generalised mixed-effects model approach will be used in the analysis of repeated measures for continuous and categorical outcomes. Mixed-effects models take into account the inter-individual differences in intra-individual change with repeated responses and use all the available data on each subject. Mixed models are also unaffected by randomly missing data and therefore do not require imputation methods[46]. The model building strategy will include fitting nested models by sequentially adding blocks of predictor variables: socio-demographics, co-morbid disorders and factors related to health service interventions. Interaction terms that are considered to be potentially important from a clinical perspective will be tested and remain in final models if significant. Predicted estimates of outcomes at each time point will be calculated using fitted models of the data in order to examine patterns of individual change. To interpret effect sizes and precision for categorical outcomes, odds ratios and confidence intervals will be calculated.

Discussion

The NTHFI-CA represents one of a few opportunities offered for longitudinal studies designed to extract data that informs service development. Information gathered has to be relevant for current and future needs. It is difficult to determine service factors beyond 5 yearly intervals. To compensate for this, there have been measures taken to set infrastructure and standardise protocols to facilitate episodic updates in information as well as ensuring reproducibility of study design and implementation. With the actual study design a series of steps were taken. The first step was establishing basic principles for defining the disease (Box 1, Appendix A). The second step involved standardising principles for attributes in KPI i.e. care dimensions (Box 2.1, Appendix B & C) and the study care domains to be tested, in this case 6 (Box 2.2). The third step involved addressing the broad NT health goals and research conduct in Indigenous population to steer implementation within 5 key priorities (Box 2.3). The fourth step is design of disease management systems in the NT context from the available evidence (Box 2.4, Appendix D). The specific details are explored.

The ACC/AHA has released several position statements to standardise the process of developing, assessing, implementing performance measures and disease management systems[30-33]. From this consensus driven platform, we identified the target disease, population and explored standardised measures that inform the observation for the required time period. The NTHFI-CA is defined for all stages and causes of CHF, for NT resident population who receive care within 6 domains of treatment. This broad definition partly relates to uncertainties on actual CHF demographics, and as the yearly admission are unlikely to exceed 500, will not lead to significant difficulties in enrolment. To determine the performance measures we again explored the position statement. The authors rated 27 potential measures on 13 dimensions using a 5-point Likert scales[32]. If a KPI received full committee support with a score of at least 3, it was advanced. The process concluded with 7 inpatient and 12 outpatients' measures. These KPI informed five dimensions of care encompassing; diagnostics, patient education (including prognosis and aetiology), treatment, and self-management (for inpatient and outpatient) and monitoring of disease status (for outpatients only)[32]. This statement did not however focus on outcomes as the design was shaped to assist physicians improve care. We have included outcomes, as this is the strongest indicator for funding for vulnerable groups beyond the conventional block funding models. To determine the final KPI several additional points were considered:

Comment [I1]: Reviewer 2b: Sentences recosntructed

I. *Existing Studies:* Several recent databases stand as land mark achievements in HF epidemiology and have confirmed clinical understanding of evidence base and positive outcomes[10-12,36,38,44]. Interestingly Krumholz etal[31] pointed out a disparity between what is conventionally accepted evidence and its generalisabilty. This is particularly so for the NT where there are significant non-traditional factors that impact on the delivery of evidence based care and affect outcomes. While it would be unreasonable to propose reconducting large CHF studies to incorporate an increasingly diverse group of patients we have come to realise that at the heart of these matters is developing an intrinsic understanding of the underlying regional demographic differences and service delivery dynamics to be able to formulate informed decisions in implementing the necessary measures, be they simple or more complex. Developing the necessary KPI in these settings is a challenge as there is a divide between perceived optimal care and, realistic and deliverable care that is in fact optimal for the region. From this it was evident that some measures needed to be rested (e.g. treatment optimization) and others added (e.g. the dimension of technology).

II. *NT Experience:* The CASPA study was ground breaking in the sense that it allowed for the first time exploration of ACS/cardiovascular KPI in Central Australia. The list was formulated from an extensive search of available national and international clinical guidelines, national health priority area indicators and reports and with reference to National Health Performance Committee guidelines and further augmented by performance measures used in published quality improvement projects. 3 priorities - process of care, target achievement and outcome indicators for the treatment and prevention were generated. This list underwent scrutiny by 60 key stakeholders, key external content experts and the research team through mailed questionnaires and a workshop convened in Alice Springs. Each stakeholder was asked to grade each potential indicator according to a number of criteria: Strength of evidence; feasibility of measurement; plausibility of effects from quality improvement; impact on outcomes; and an assessment of the overall utility of the measure. Results were collated and analysed for each indicator (overall grading) and for each of the five criteria across each indicator. Indicators that were graded as high priority, frequently recorded, very plausible and will have a large impact or better were included in the final list (average score on grading scale ≥ 4.0). Indicators that demonstrate an across criteria grade of less than 4, but was assessed by key stakeholders as a high or essential priority within the overall (utility) rating, were scrutinised by the project team and included as decided by consensus. Data specifications were then developed according to internationally standardised definitions. Subsequent data collection tools were developed and piloted in a number of hospital and PHC records (n=20) and implemented. The spill over knowledge assisted greatly in the NTHFI-CA design.

Combining this local and international experience, with the standardized ACC position[32], a conceptual framework KPI reflecting 6 critical domains for treatment delivery and 5 principal dimensions of care evolved (Box 2). All these well established performance measures were individually scrutinised and included or rested. Level of evidence was the predominant scrutinizing theme in the second phase. The less validated 'local knowledge' and NT health priorities were additional considerations. Study investigators made the decisions on these. Several less well established indicators were included through recent understanding and development of self-management and IT based solutions[15]. In direct contrast to intervention themed databases[35,36] focus on specifics in the treatment dimension was given a lower priority (see appendix E, F). Box 4 describes this in greater detail.

Further rationale for specific KPI inclusion or exclusion are as follows: Domain 1: Demographics are at the heart of this study. Validated KPI derived from CASPA were used to extract race, culture, language and support networks; further expansion was made in the dimension of HF aetiology with emphasis on ischemic, hypertensive as well as rheumatic and alcohol induced causes. Data on tertiary referral centres were collected, as there were 2 main cardiac surgical referral hospitals. Decision referral patterns vary with the treating physician practices as well as waiting list and urgency. It is established that decisions on percutaneous or surgical revascularisation and valvular restoration or replacement differs at these sites on physician, group consensus and expertise at the respective sites. Details on primary care physician, pharmacy, residence and principal next of kin were deemed important as local and ethnicity were deemed factors in service uptake and delivery. Furthermore access to primary care could determine - admission, readmission burden and early measures to prevent deterioration; Domain 2 -5: A comprehensive past medical history of all systems were included to establish the overall need for chronic medical service needs and factors preventing use or uptake of HF pharmacology, cardiac rehabilitation or referral for invasive management. Biochemistry details were included to establish pattern of establishing HF aetiology and outpatient risk for adverse events. Methods for estimating eGFR was obtained as much recent work raises validity of estimated measures with illness and demographics, which subsequently alter prescribing

practices and outcomes[12,13,45]. KPI for depression were expanded as a high burden was noted in CASPA, this also being a significant factor in many dimensions of self-care and compliance. In hospital, discharge and outpatient indicators were designed to reflect potential blocks to maximising proven pharmacological prescription and access to cardiac rehabilitation, at the core of these were reasons for non-prescription or sub-therapeutic prescription. The actual specifics on medication titration across all domains were rested. It is noted that care and resources are needed to titrate many variables in CHF care, for e.g. ββ and ACE-I (Appendix E &F). This information can be extrapolated from frequency of contact with medical practitioner and central pharmacy prescription slips. Appropriate early therapeutics - to prevent further heart muscle damage, good symptom relief and minimising iatrogenic adverse effects such as renal dysfunction and electrolyte derangements is within the control of the health systems and builds client confidence, and is considered vital, this dimension was included. Domain 6: Overall we felt, in the community, that the greatest value in the performance measures related to 2 critical aspects - impacts on the overall health system (strain and morale) and contributors to poor outcomes (client and non-client). Post hospital access to services and blocks to referrals (non client) and self-management (client) are factors related to efficiency, planning and client education. Investment in these dimensions would not increase strain on resources, with potential benefit.

Data collection instrument was via Case Report Forms (CRF) designed for a combination of retrospective and prospective audit from combination of several studies CASPA and WHICH. The Baker IDI, Flinders University, and SAHMRI have extensive track record in electronic CRF. This was greatly beneficial and reduced challenges faced for stage 2. At present much research work is conducted through the Menzies School of Health Research. As part of this initiative we have began the process of developing dedicated office to conduct studies across the cardiac and renal axis. Part of this also involved staff training in good clinical practice and transfer of knowledge form partners to stand as an independent entity*.

Indigenous health in the NT requires special focus. Australia has seen the first Indigenous premier in 2013 and a measured but controversial statement of removing the Indigenous ministerial portfolio was “there are numerous ministers for many areas and one for all Indigenous affairs”. Current sentiments that move away from race based programs are encouraged but with caution. We clarify that out approach does not target any specific communities but is based on needs. It is unfortunate that disadvantaged communities are also marginalised in large studies partly for language, cultural and perceived compliance issues. In this case the Indigenous community represent a significant group in Australian society who have despairingly worse outcomes. The desire to preserve ones traditional culture in an ever modernising world proves huge challenges for these communities and health systems. Poor understanding could lead to stereotyping that could brand some behaviour as recalcitrant, adding to the vicious circle. Respecting these beliefs and tailoring care in lieu of these factors we were able to advance the CASPA study. This was done through acknowledgement as several sensitive areas in the ethics application; *Equality* - The overarching aims of the research project is based within a framework driven by questions of equality in the provision of health care across the continuum for all patients regardless of ethnicity, gender or age, and one based on need as demonstrated by clinical determinants; *Survival and Protection* - We also recognise that chronic disease research and epidemiology has tended to contribute to deficit approaches to individual pathology; that is disease is due to bad behaviour. Less focus has been afforded the potential successes and

* *Information on our partners and expertise can be found on the web or via corresponding author.*

failures in health systems, as contributors to differential outcomes for populations based on ethnicity; *Respect* - "We feel that information generated within this project and the processes developed have the potential to contribute to community directed health service redevelopment and quality improvement activities; *Reciprocity* - We feel that this work may identify failures in health systems and therefore identify obligations that are being unmet by systems themselves; *Responsibility* - Re-framing the gaze of health inequality, from individual focused deficits to system failures stands as the key principle on which this extensive work is based, and is a direct effort at ensuring that exploring health inequalities does not undermine and harm Indigenous individuals and communities. These principles may play great importance to future research practices in these areas.

Interim analysis will be conducted at the 6-month mark. It is anticipated at this point lessons learnt and spill over knowledge from the ongoing CASPA-ACS intervention study may direct minor modifications to the existing CRF. One such area is increasing the KPI in domains 1, 2 and 6 to better understand the barriers to accessing primary care. CHF, an ambulatory case sensitive condition, can largely be managed in the community with the application of appropriate and timely preventive care and early disease management. The issues that remain unclear at this point are the adequacy and the barriers for accessing such care in each of the remote communities. Of interest, Ansari etal noted that a lack of timely and effective care had an impact on admission rates in rural Victoria particularly among lower socio-economic groups[47,48]. A similar understanding in the NT could impact on how we allocate resources in the future.

Comment [I2]: Reviewer 1a: New paragraph added references provided

Measuring performance is not an end in its own right and clinical indicators and their measurement alone are not sufficient to change behaviour in service provision and quality improvement. They must be supplemented with key educational activities (e.g. provision of continuous and sustained feedback of results to all levels of service provision), processes to sustain continuous monitoring and assessment and to inform policy development on a local and regional level. Clearly defined dissemination processes and involvement of Aboriginal Health Workers, hospital and community based nurses, allied health professionals and clinicians are essential if practice is to change. Engaging non-governmental (NGO) service providers, data coders, quality improvement staff, NGO's (NHF NT Division, Healthy Living NT), Division of General Practice/Primary Health Care and consumer representatives in the development phase of the project so as to ensure alignment between proposed indicators and local needs. The dissemination of key findings through key advisory/research institutions will also increase the awareness nationally/globally and build foundations for future competitive research funding. Finally, we also have been in negotiations for the broader applicability of the findings of and tools utilised within this project with the Australian Collaborative Project (which seeks to measure PHC performance). This stands as a critical method of project outcome dissemination.

Comment [I3]: Reviewer 2b: Sentences recosntructed

Limitations:

Conducting clinical studies in the NT is in itself a limitation; firstly, the realization of non-traditional risks factors, which impact on management; secondly, as there are few benchmarks as comparators; and finally shortfalls in research funding and infrastructure. While no system has the perfect mix of resource input to match service needs to answer this question, for this region, there will be components within many aspects of the study that is hypothesis generating, compared to the mainstream. Nonetheless following the accepted consensus and providing enough information to allow reproducibility is accepted as a positive means for overcoming this limitation. Examples of this were resting KPI that collate in depth information on medication dosing as per RCT's

and large HF databases[31-39]. This study will not address whether clinical trial prescribing practices are achieved, instead we are keen to determine if there is a system in place to facilitate this, which will be answered. The infrastructure is also in place for the next step to determine if this can occur. We note that RCT level outcomes relate to achieving prescribing practices in the trials. As examples Appendix E/F, highlight differences in just 2 medications. *As noted, ββ titration is ideally done at 2 weekly intervals and may not need biochemistry, while ACE-I can be done at 3-7 day intervals and usually require assessment of basic biochemistry. Addition of aldosterone blockers and other agents are further complexities*. We are hopeful that relevant information on this will help steer the next phase, an intervention audit. This study relied on lessons from ACS study conducted greater than 5 years ago. Unanticipated changes that cannot be standardized could act as confounders, which will only be revealed in time; e.g. is potential drop off rate during follow-up. In the standardization of design – we did not use 5 point Likert scale, as the number of NT consultants was only 4. In addition the CHF task force position was comprehensive[32]. Finally, clinical practice guidelines are well established, as Krumholtz stated "guidelines are written in a spirit of suggesting diagnostic or therapeutic interventions for patients in most circumstances. Accordingly, significant judgment by clinicians is required to adapt these guidelines to the care of individual patients to ensure accountability in these judgments an evidenced based process is important". The standardizing of clinical judgment and interpretation of guidelines remains contentious and may be more noticeable with fewer cardiologists. As such we intentionally left the criteria for KPI reference broad. This will be narrowed, as lessons are learnt and early data are analyzed. This should aid more focused and detailed assessments in the future.

∗ We have not provided treatment pathways for AICD/CRT/ other pharmacotherapies. These are available from several optimizing databases (34,35,37).

Conclusion

Achieving optimal care in the remote setting is no different from urban settings. The ability to provide a continuum of care from presentation to post discharge requires activation of proven KPI at each level of care. The significant differences in remote care revolve around the interaction of service infrastructure, personnel, disease burden and cultural sensitivities. As such the outcomes limiting factors are variable and require exploration. The potential gains of these findings in implementing early and later secondary prevention of CHF and its sequelae are undisputed. In addition, little information exists on the provision and outcomes for CHF initiatives for indigenous populations, which are a significant client base in the remote setting. Even less is known about the post-discharge care. The extent to which care is sub-optimal and the acute and long-term HF management among Aboriginal clients could be contributing to the large and growing cardiovascular mortality differentials seen between Aboriginal and non-Aboriginal clients. Thus the development of meaningful, sustainable public health, clinical and continuous quality improvement policy in the provision of CHF care in the NT requires urgent attention, and must be used to drive the development of better service delivery at both the individual and health system levels. It is anticipated that this work will highlight key areas of disparity and inform the implementation of an intervention study.

Abbreviations

ACE-I – Angiotension Converting Enzyme Inhibitor

ACS – Acute coronary syndrome

ADHF – Acute decompensated heart failure

ASH – Alice Springs Hospital

ββ - Beta Blockers

CASPA – Central Australian Secondary Prevention of Acute Coronary Syndrome Study

CASPA-HF – Central Australian Secondary Prevention of Acute Heart Failure Study

CHF – Congestive Heart Failure

CRF – Case Report Form

CVD – Cardiovascular Disease

DHCS – Department of Health and Community Services

ICD – International Classification of Diseases

KPI – Key Performance Indicators

NGO – Non-Governmental Organisations

NHF – National Heart Foundation

NT – Northern Territory

NTHFI – CA - **N**orthern **T**erritory **H**eart **F**ailure **I**nitiative **– C**linical **A**udit

PHC – Primary Health Care

RCT – Randomized Controlled Trial

RDH – Royal Darwin Hospital

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BOX 1: ICD 10 Diseases of the circulatory system. Primary screening includes codes I42, I43 and I50. Secondary screening involved ADHF during index admission with highlighted codes

ICD-10-CM Code	Primary classification (I42,I43,I50) Description
I42.0	Dilated Cardomyopathy
I42.1	Chronic systolic (congestive) heart failure
I42.2	Acute on chronic systolic (congestive) heart failure
I42.3	Unspecified diastolic (congestive) heart failure
I42.4	Acute diastolic (congestive) heart failure
I42.5	Chronic diastolic (congestive) heart failure
I42.6	Acute on chronic diastolic (congestive) heart failure
I42.8	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I43	Cardiomyopathy is diseases classified elsewhere
I50.1	Left heart failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.9	Heart failure, unspecified

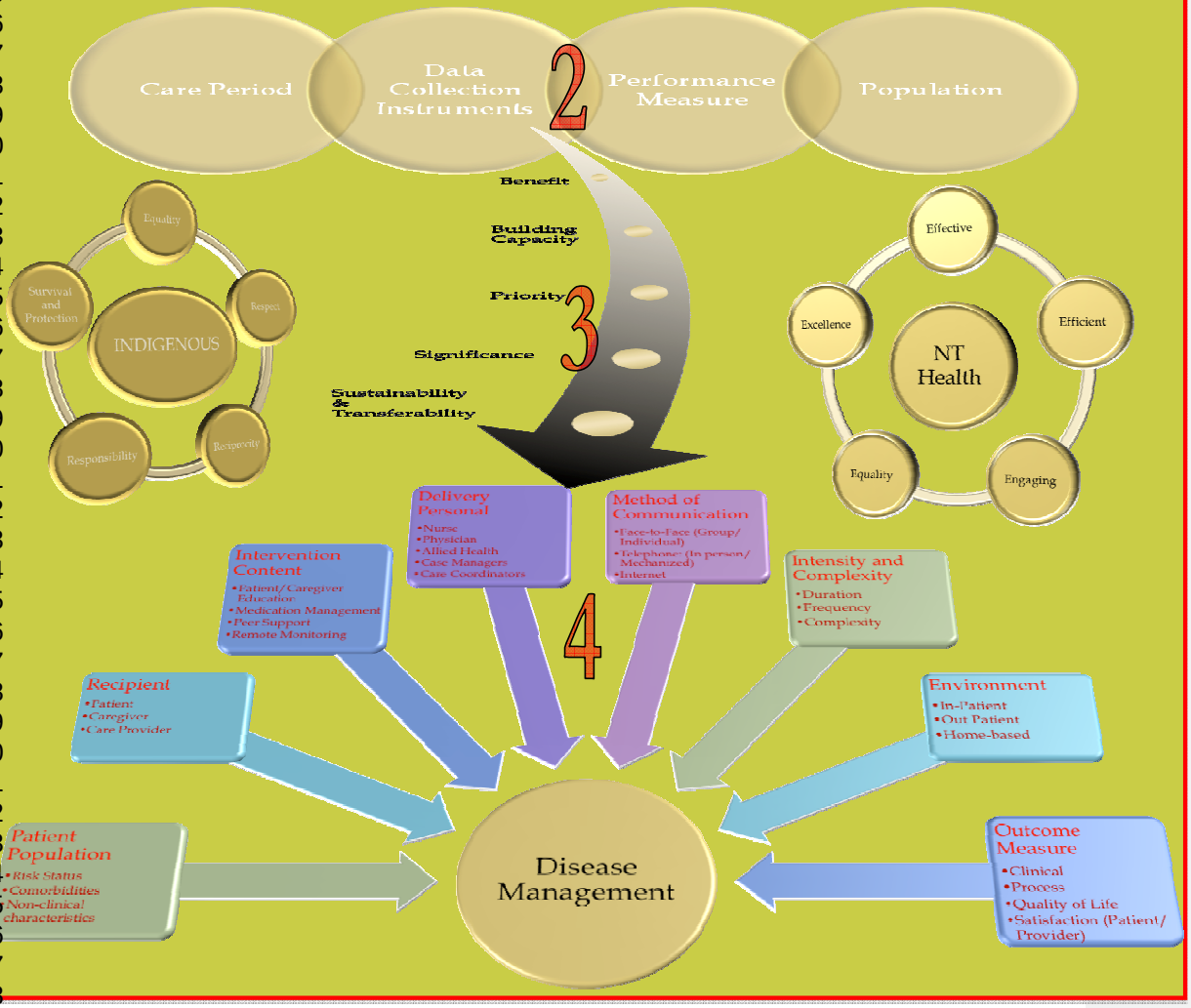
ICD-10-CM Code	Secondary Acute Heart Failure with these Admission Codes Description
I00-I02	Acute Rheumatic Fever
I05-I09	Chronic Rheumatic Heart Disease
I10-I15	Hypertensive Heart Diseases
I20-I25	Ischemic Heart Diseases
I26-I28	Pulmonary Heart Disease and Diseases of Pulmonary Circulation
I30-I32	Pericardial Diseases
I33-	Endocardial Diseases
I34-I39	Nonrheumatic valve disorders
I40-I41	Myocarditis
I44-I45	Conduction system Disorders
I46	Cardiac Arrest
I47-I49	Tachyarrhytmias
I70-I79	Diseases of arteries, arterioles and capillaries
I80-I89	Diseases of veins, lymphatic vessels and lymph nodes, not elsewhere classified
I95-I99	Other and unspecified disorders of the circulatory system

BOX 2 Design of the NTHFI-CA involved 4 steps: 1 – using a set of standardised principles (blue box) and their attributes (green box) we formulated outlines for each performance attribute (final column). CASPA shaped many aspects of design and implementation attributes; 2 - four basic factors shaped the broad study outline; 3 – highlights the ethical considerations for studies in the NT; 4 – broad disease management goals for which performance measures hope to inform. (Ref 30-33)

Principles and Recommendations From the AHA's Expert Panel on Disease Management
1. The main goal of disease management should be to improve the quality of care and patient outcomes.
2. Scientifically derived, peer-reviewed guidelines should be the basis of all disease management programs. These guidelines should be evidence based and consensus driven.
3. Disease management programs should help increase adherence to treatment plans based on the best available evidence.
4. Disease management programs should include consensus-driven performance measures.
5. All disease management efforts must include ongoing and scientifically based evaluations, including clinical outcomes.
6. Disease management programs should exist within an integrated and comprehensive system of care in which the patient–provider relationship is central.
7. To ensure optimal patient outcomes, disease management programs should address the complexities of medical comorbidities.
8. Disease management programs should be developed for all populations and should particularly address members of underserved or vulnerable populations.
9. Organizations involved in disease management should scrupulously address potential conflicts of interest.

1

ACC/AHA Attributes for Satisfactory Performance Measures (Appendix A/B)		NTHFI-CA
Useful in improving patient outcomes	1. Evidence-based 2. Interpretable 3. Actionable	Ref 28-30
Measure design	1. Denominator precisely defined	Inclusion/Exclusion
	2. Numerator precisely defined	Yes CHF
	3. Validity - Face validity - Content validity - Construct validity	CASPA
	4. Reliability	CASPA
Measure implementation	1. Feasibility - Reasonable effort - Reasonable cost - Reasonable time period for collection	CASPA
Overall assessment		Pending



Box 3 Trial Protocol and Study Pathways

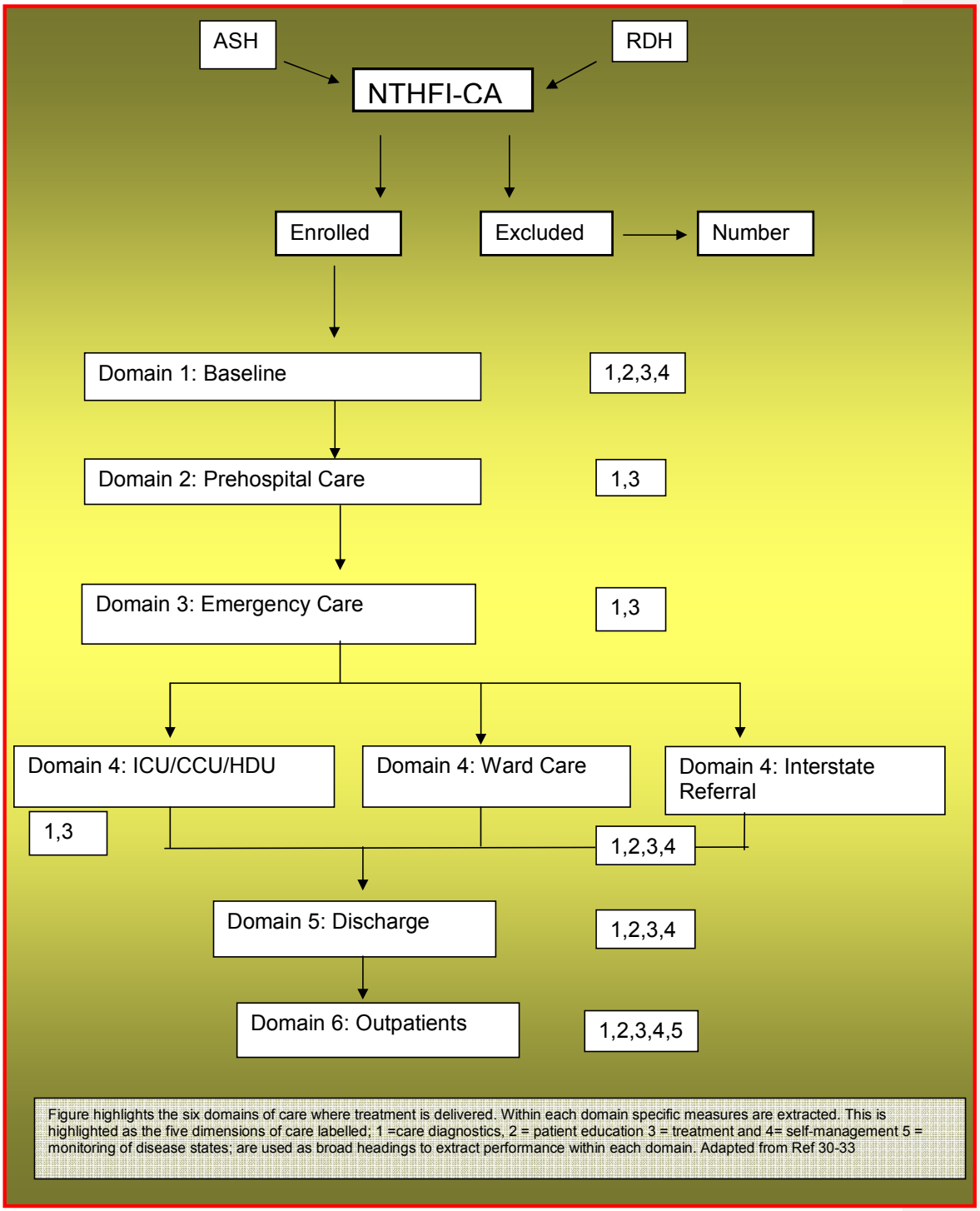


Figure highlights the six domains of care where treatment is delivered. Within each domain specific measures are extracted. This is highlighted as the five dimensions of care labelled; 1 =care diagnostics, 2 = patient education 3 = treatment and 4= self-management 5 = monitoring of disease states; are used as broad headings to extract performance within each domain. Adapted from Ref 30-33

Box 4 Performance measures within each treatment dimensions divided into mild and moderate or greater ADHF (Ref 31,32)

Domain	1 χ	2 δ	3	4	5	6 ε
CHF						
Mild	1.1-14 2 3.1-13 4	1.1-7 3.1-7	1.1-13 3.1-8	1.1-14 2 3.1-8 4	1.1-7,14 2 3.1-7 4	1.1-14 2 3.1-13 4 5
Mod +	1.1-14 2 3.1-13 4	1.1-7 3.1-.8	1.1-14 3.1-10	1.1-14 3.1-13	1.1-7,14 2 3.1-7 4	1.1-14 2 3.1-13 4 5

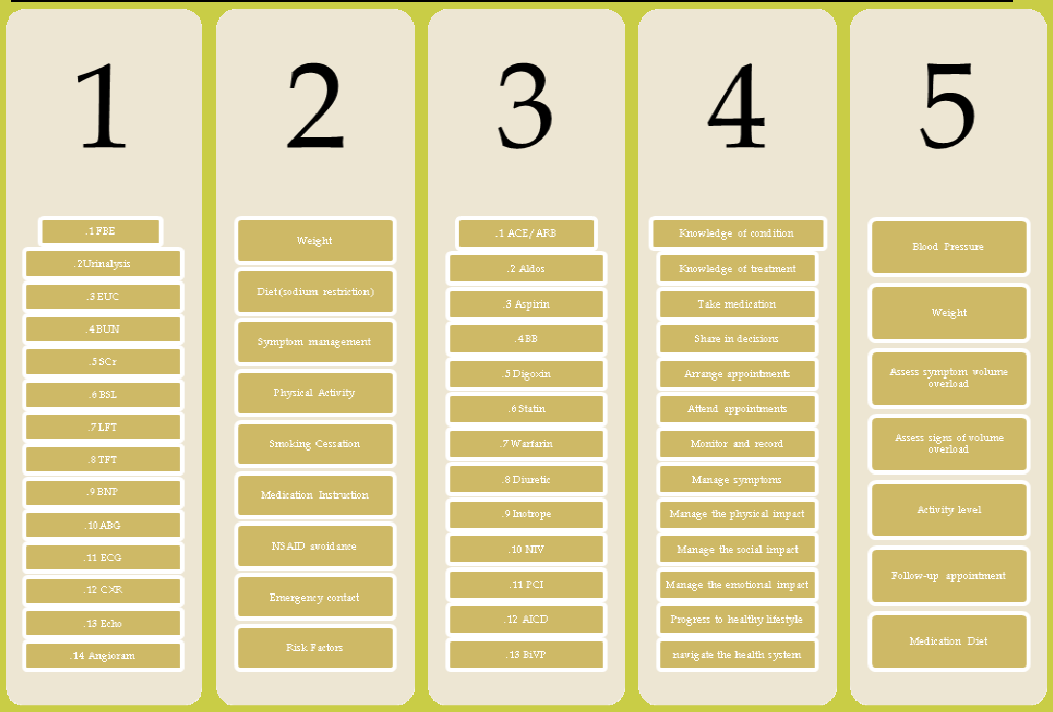


Figure provides a detailed description of the performance measures assessed within each of the five dimensions of care. The measures omitted are described in more detail in the discussion section of this paper.
χBNP – Appendix 2; ICER unknown
δPoint of care devices variably available in different communities
εIndigenous patients remote PPM monitoring
Dimension 1: Standard blood tests, electrolytes, renal function, liver function, arterial blood gas
Dimension 3:ACE/ARB/Aldos – Renin Angiotensin system blockers – ACE-i titration see appendix 4; ββ -beta blockers - titration see Appendix 5. AICD – automated implanted cardioverter defibrillator; BiVP – biventricular pacemaker; NIV – non invasive ventilation; PCI – percutaneous coronary intervention
Dimension 4: There are 14 essential action points; only principles are listed in this box (see appendix 6)
Dimension 5: 7 vital action points for monitoring of heart failure

Figure highlights the six domains of care where treatment is delivered. Within each domain specific measures are extracted. This is highlighted as the five dimensions of care labelled; 1 =care diagnostics, 2 = patient education 3 = treatment and 4= self-management 5 = monitoring of disease states; are used as broad headings to extract performance within each domain. Adapted from Ref 30-33

APPENDIX A DEFINITIONS FOR Acute CHF and Stages (Ref 40)
(BNP based definitions not used, as it is not available in the NT for acute use)

Clinical Presentation	Incidence*	Signs and Symptoms	Characteristics
1. Elevated systolic blood pressure	>50%	Usually develop abruptly	Predominantly pulmonary (radiographic/clinical) rather than systemic congestion due to rapid fluid redistribution from systemic to pulmonary circulation; many patients have preserved EF
2. Normal systolic blood pressure	>40%	Develop gradually (days or weeks) and are associated with significant systemic congestion	Despite high ventricular filling pressure, radiographic pulmonary congestion may be minimal because of pulmonary vasculature/lymphatics adaptation due to chronic elevated left atrial pressures
3. Low systolic blood pressure (90 mm Hg)	<8%	Usually have a low cardiac output with signs of organ hypoperfusion	Many of those patients have advanced or end-stage HF
4. Cardiogenic shock	<1%	Rapid onset	Primarily complicating acute MI, fulminant myocarditis
5. Pulmonary edema	<3%	Rapid or gradual onset	Clinical: severe dyspnea, tachypnea, tachycardia, and hypoxemia, requiring immediate airway intervention Radiographic: present in up to 80% of patients; often not associated with clinical pulmonary edema
6. “Flash” pulmonary edema	?	Abrupt onset	Precipitated by severe systemic hypertension. Uncorrected, respiratory failure and death ensue. Patients are easily treated with vasodilators and diuretics. After blood pressure normalization and reinstitution of routine medications, patients can be discharged within 24 h
7. Isolated right HF	?	Rapid or gradual onset	Not well characterized; there are no epidemiological data (eg, acute cor pulmonale, right ventricular infarct)
8. Acute coronary syndromes (25% of patients have signs/ symptoms of HF)	?	Rapid or gradual onset	Many such patients may have signs and symptoms of HF that resolve after initial therapy or resolution of ischemia
9. Post–cardiac surgery HF	?	Rapid or gradual onset	Occurring in patients with or without previous ventricular dysfunction, often related to worsening diastolic function and volume overload immediately after surgery.

STAGE	Description
A	Patients at high risk for HF but without structural heart disease or symptoms of HF (e.g., patients with hypertension, atherosclerotic disease, diabetes, obesity, and metabolic syndrome or patients using cardiotoxins or with a family history of cardiomyopathy). Such patients have no identified structural or functional abnormalities of the pericardium, myocardium, or cardiac valves and have never shown signs or symptoms of HF.
B	Patients who have developed structural heart disease that is strongly associated with the development of HF (e.g., previous myocardial infarction, LV remodeling including LVH and low EF, or asymptomatic valvular disease) but without signs or symptoms of HF.
C	Patients with structural disease who have current or prior symptoms of HF (e.g., known structural heart disease and shortness of breath and fatigue, reduced exercise tolerance).
D	Patients with refractory HF requiring specialized interventions (e.g., marked symptoms of HF at rest despite maximal medical therapy—those who are recurrently hospitalized or cannot be safely discharged from the hospital without specialized interventions).

APPENDIX B Attributes of Performance Indicators (Ref 32)

Choosing Performance Measures	
Selection Factors	**Considerations**
Adherence to the potential performance measure results in meaningful improvements in clinically important outcomes	Evidence-based trials, strong clinical practice guideline recommendations for (Class I, Level of Evidence: A) or against (Class III, Level of Evidence: A) the measure
Broad sampling from multiple domains associated with the process of medical care (see Figure 1)	Measures should be distributed across the domains of diagnosis, patient education, treatment, patient self-management, and serial monitoring of success of treatment
Attributes of Selected Measures	
Measure Characteristics	**Relevant Attributes**
Useful in improving patient outcomes	Interpretable Actionable
Measure design	Denominator precisely defined
	Numerator precisely defined
	Established types of validity
	• Face
	• Content
	• Construct
	Established reliability
Measure implementation	Feasibility
	• Reasonable effort
	• Reasonable cost
	• Reasonable time period for collection
Overall assessment by Performance Measures Writing Group	Overall assessment of measure by explicit, predefined criteria for inclusion in measurement set

Adapted from Normand SL et al.[2]

APPENDIX C Choosing Performance Indicators (Ref 32)

Choosing Performance Measures	
Selection Factors	**New Considerations**
Confidence that adherence to a potential performance measure would result in meaningful improvements in clinically important outcomes	The methodology and logic by which a performance measure was selected, with a clear description of anticipated benefits on meaningful clinical outcomes, should be disclosed by the writing committee.
Costs of measure	Explicit demonstration that application of the performance measure to patients is associated with an acceptable ICER.
	An estimate of the societal burden of more complete adherence to the performance measure.
Outcomes measures	The outcomes to be considered must be clinically relevant, including mortality, irreversible morbidity, and health status (symptoms, function, and quality of life), and surrogate outcomes should be avoided.
	Previously published recommendations for publicly reported outcomes should be followed.[22]
	Risk adjustment, with carefully selected clinical variables and explicit consideration of demographic characteristics, must be available to render observations interpretable.
	Where possible the population should represent a disease state rather than a procedure applied to a subset of that population.
Measure Characteristics	**New Considerations**
Use of exceptions	Exclusions of patients from the denominator of a performance measure are reasonable and should be broadly grouped into • medical • patient • system-based reasons for why the patient was not eligible
No. of measures	To minimize the number of measures, efforts at creating a national consensus, involving all stakeholders, on measures to be used for a specified period of time for accountability, pay for performance, and quality-improvement efforts should be developed.
	Although performance measure writing committees should create a full complement of measures for a disease, the NQF should select only a subset of these for use at any particular time.
	The subset should include measures from multiple dimensions of care to facilitate a more complete assessment of quality.
	Measures should be retired when new evidence questions the association of those measures with clinically meaningful outcomes or performance is so high that there is little room for future improvement.
	Retired measures should be considered for reassessment in future years.
Feasibility of data collection	Data collection should occur prospectively through routine transactions of medical care because retrospective collection of data is not sustainable.
	EMR companies need to create and support export of data using standardized formats so that a greater number of providers can participate in national quality-assessment programs.
	Measures need to be developed in a way that recognizes the longitudinal patient care experience and creates "windows" for capturing performance that are practical and clinically interpretable.
Composite measures	The psychometric properties of these measures, including reliability, accuracy, and predictive validity, should be demonstrated.
	The purpose, intended audience, and scope of a composite measure should be explicitly stated.
	The individual measures used to create a composite measure should be evidence-based and reliable.
	The methodology used for weighting and combining individual measures into a composite performance measure should be transparent and empirically tested.
	Composite performance measure reporting by providers should include a measure of the degree of uncertainty surrounding composite estimates.
Attribution	Accountability is an important opportunity to improve practice.
	It is essential that those held accountable have the processes of care being assessed under their locus of control.
	More methodological work is needed for promotion of the concept of shared accountability for evaluating transitions in care.

EMR indicates electronic medical record; ICER, incremental cost-effectiveness ratio; and NQF, National Quality Forum.

Appendix D Heart Failure Disease Management Scoring System (Ref 33)

Table. Heart Failure Disease Management Scoring Instrument

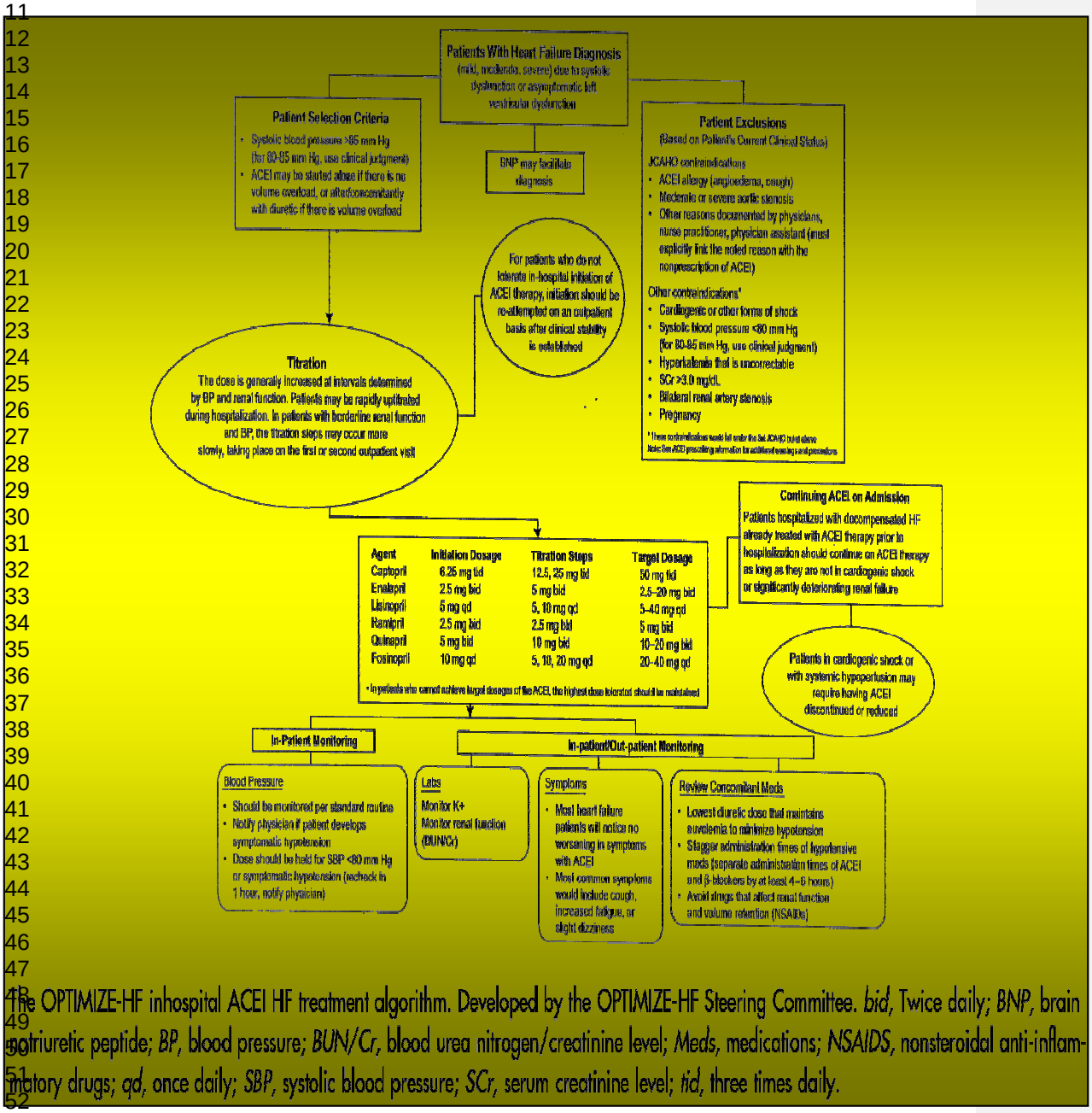
Intervention Category	Points to be Assigned	Comment/Rationale
Recipient	1=Provider alone 2=Patient alone 3=Patient with some inclusion of caregiver 4=Patient with a caregiver who is central to the intervention	Most interventions focus on the patient; yet, coding scheme recognizes that some interventions are aimed at improving provider behavior (eg, system intervention aimed at evidence-based care). Most points are given to interventions that focus on the patient but also include caregivers because an engaged family member act as 2nd set of eyes and memory support, which can deter hospitalization. Thus: 2 points assigned if focus was on patient alone; 3 points if there is some inclusion of the caregiver, 4 points if inclusion of the caregiver was a major component of the intervention.
Intervention content		
Education and counseling aimed at supporting self-care	0=No mention of education 1=Focus solely on importance of treatment adherence 2=Focus on treatment adherence including some creative methods of improving adherence 3=Focus on surveillance but no mention of actions to be taken in response to symptoms (eg, no flexible diuretic management) 4=Emphasis on surveillance, management, and evaluation of symptoms in addition to treatment adherence	Interventions are derived from Krumholz et al,[5] with point allocations assigned to reflect current literature that suggests these interventions are not comparable in efficacy. Individualized patient education and counseling is essential because patients must be engaged in the process of self-care and helped to learn how to make decision about managing their HF. However, true self-care is more than treatment adherence.
Medication management	0=No mention of medication regimen 1=Some mention of medications (eg, importance of medication compliance) but not an active part of the intervention. No attempt to intervene with provider to get patients on an evidence-based medication regimen 2=Evidence-based medication regimen advocated but no follow-up with patient or provider to monitor the suggestion 3=Medication regimen monitored, attempt made to get the patient on evidence-based medications, with follow-up monitoring done with patient or provider	Patients on optimal, evidence-based therapies are significantly less likely to have acute exacerbations and hospital admissions.
Social support Peer support	0=No mention of a peer support intervention 1=Peer support mentioned but not integral to intervention 2=Peer support integral component of intervention	Peer support interventions not used commonly but when used they appear to improve perceived support rather than self-care. Support has been conceptualized as a moderator of the relationship between intervention and outcome.
Surveillance by provider: Remote monitoring	0=No use of remote monitoring or telehealth 1=Remote monitoring is used in conjunction with other interventions that form the main intervention used 2=Telehealth is essential component of intervention	Remote monitoring is distinguished from other methods of communication. Video monitoring may become a common method of communication. For now, remote monitoring is conceptualized as method of engaging patients in process of learning self-care by active engagement.
Delivery personnel	1=Single generalist provider (eg, physician, nurse, pharmacist)	Generalist: Provider specifically noted to not have training in heart failure.
	2=Single HF expert provider (eg, physician, nurse, pharmacist)	Multidisciplinary interventions: Multidisciplinary team involved with all or most patients.
	3=Multidisciplinary intervention	Integrated/choreographed multidisciplinary intervention: Provided by multiple disciplines in collaboration; provided in an HF clinic with policies/protocols specified for HF care.
	4=Multidisciplinary intervention provided in an integrated, choreographed manner	Optimal mix of program delivery personnel is not known, thus assigned points are hypothesized in this study.
Method of communication	1=Mechanized via internet or telephone 2=Person-to-person by telephone 3=Face-to-face, individual, or in a group 4=Combined: Face-to-face at least once alone or in a group with individual telephone calls in between meetings	Most interventions involve combined individual approach with telephone/face-to-face contact. Points should be assigned based on predominant method of communication The method of communication varies widely within individual HF disease management programs, making it difficult to judge how the method influences outcomes. Thus, assigned points are hypothesized in this study.

Table. *Continued*

	Points to be Assigned	Comment/Rationale
Intensity and complexity		Some literature suggests that more intense, complex, and lengthy interventions are associated with better outcomes, though simple interventions have also been effective. Two categories were created to capture this item: Duration and complexity.
Duration	1=≤1 mo 2=≤3 mo 3=≤6 mo 4=>6 mo	
Complexity	1=Low: single contact with little or no follow-up 2=Moderate: >1 but <4 and/or infrequent contact or contacts of short duration 3=High: multiple contacts of significant duration	Complexity is judged on frequency of content and duration of visits/calls. Assigned points are hypothesized in this study.
Environment	1=Hospital: Inpatient only 2=Clinic/outpatient setting 3=Home-based 4=Combination of settings	Krumholz et al[5] note that it is not yet clear which environmental factors are associated with success. Thus assigned points are hypothesized in this study. Many interventions are provided in a more than 1 setting, and scoring endeavors to capture these combinations.

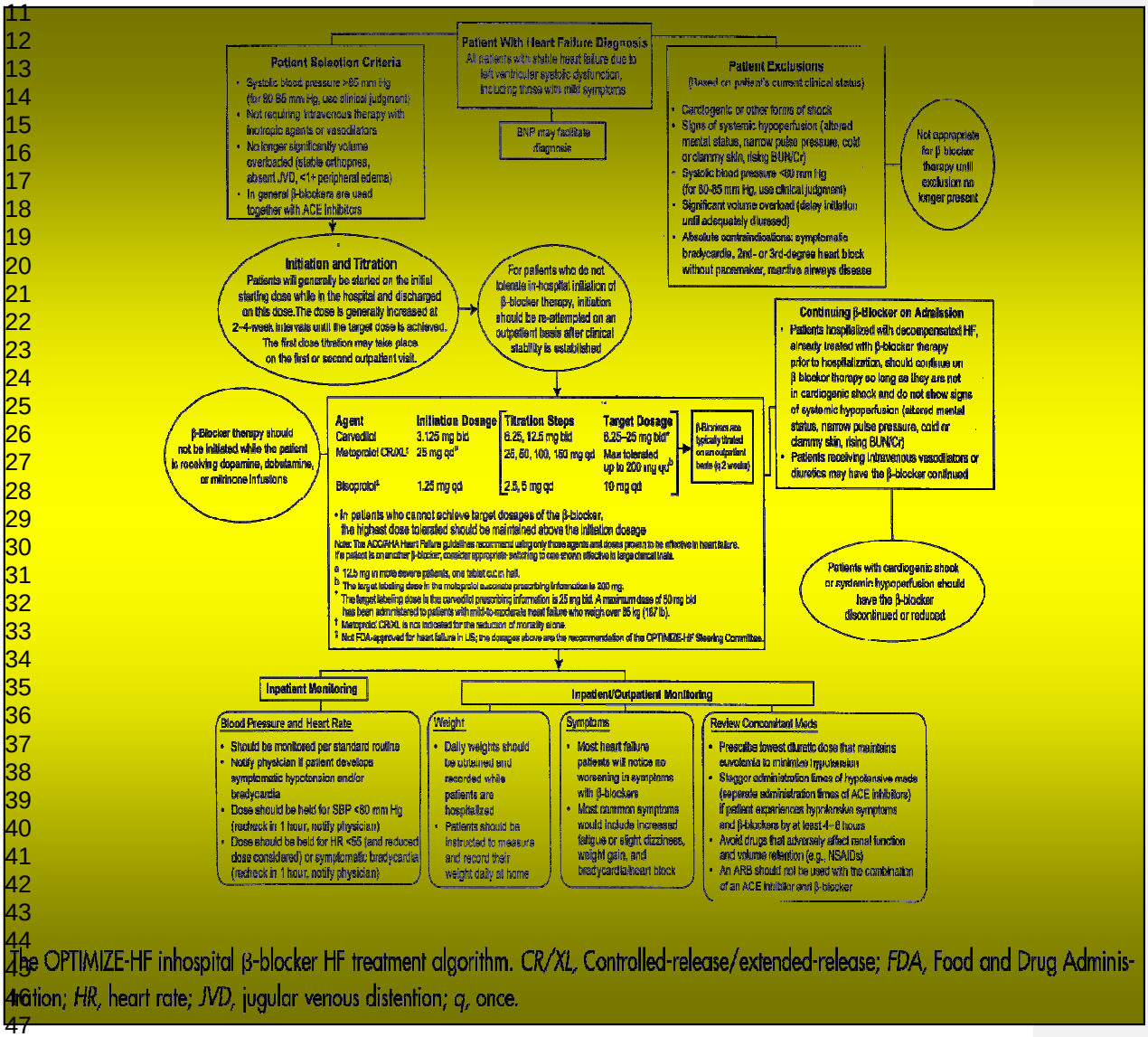
Note: All available sources describing the intervention should be used to ascribe scores.
Reprinted from Krumholz et al,[5] with permission from Lippincott Williams & Wilkins. Copyright 2006, American Heart Association.

Appendix E Model of ACE-I Titration in OPTIMIZE-HF (Ref 34)



The OPTIMIZE-HF inhospital ACEI HF treatment algorithm. Developed by the OPTIMIZE-HF Steering Committee. *bid*, Twice daily; *BNP*, brain natriuretic peptide; *BP*, blood pressure; *BUN/Cr*, blood urea nitrogen/creatinine level; *Meds*, medications; *NSAIDS*, nonsteroidal anti-inflammatory drugs; *qd*, once daily; *SBP*, systolic blood pressure; *SCr*, serum creatinine level; *tid*, three times daily.

Appendix F Model of Beta- Blocker Titration in OPTIMIZE-HF (Ref 34)



The OPTIMIZE-HF inhospital β-blocker HF treatment algorithm. *CR/XL*, Controlled-release/extended-release; *FDA*, Food and Drug Administration; *HR*, heart rate; *JVD*, jugular venous distention; *q*, once.

APPENDIX H: The Flinders ProgramTM for Chronic Condition Management Information Paper - SUMMARY (Ref 45)

The Principles of Self-management	Aim of the Flinders ProgramTM	Assessment Tools Goals
1. Have knowledge of their condition 2. Follow a treatment plan (care plan) agreed with their health professionals 3. Actively share in decision making with health professionals 4. Monitor and manage signs and symptoms of their condition 5. Manage the impact of the condition on their physical, emotional and social life 6. Adopt lifestyles that promote health 7. Have confidence, access and the ability to use support services.	1. Improves the partnership between the client and health professional(s) 2. Collaboratively identifies problems and therefore better (i.e. more successfully) targets interventions 3. Is a motivational process for the client and leads to sustained behaviour change 4. Allows measurement over time and tracks change 5. Has a predictive ability, i.e. improvements in self-management behaviour as measured by the PIH scale, relate to improved health outcomes.	1. Partners in Health Scale 2. Cue and Response interview 3. Problems and Goals Assessment • Identification of Issues • Formation of an individualised Care Plan • Monitoring and reviewing

PIH	C&R	Problem and Goals (P&G) Assessment
• Knowledge of condition • Knowledge of treatment • Ability to take medication • Ability to share in decisions • Ability to arrange appointments • Ability to attend appointments • Understanding of monitoring and recording • Ability to monitor and record • Understanding of symptom management • Ability to manage symptoms • Ability to manage the physical impact • Ability to manage the social impact • Ability to manage the emotional impact • Progress towards a healthy lifestyle • Ability to know and navigate the health system	• The C&R process uses a series of open-ended questions or cues to explore the patient's responses to the PIH Scale in more depth. E.g. • **Knowledge of Treatment** - What can you tell me about your treatment? - What other treatment options including alternative therapies do you know about? - What does your family/carer understand about your treatment? • **Sharing in Decisions** - Does your doctor/health worker listen to you? - How involved to you feel in making decisions about your health? • **Healthy Lifestyle** - What are you doing to stay healthy as possible? - What things to you do that could make your health	- The Problems and Goals assessment is another tool that can be used as an adjunct to the PIH and C&R process or as a stand-alone assessment. **Notes:** The health worker may well see one of these issues as the main or biggest problem for the client. The client may see the same thing as their biggest problem but they may see something else as having a far greater impact. For example, the clinician might think that the way the client uses their medication is the biggest problem, however the client may think their biggest problem is the demands the family places on them, perhaps they are caring for grandchildren everyday and have little time for themselves. As well as defining the problem from the client's perspective, this assessment also clearly identifies a goal or goals that the client can work towards

APPENDIX A DEFINITIONS FOR Acute CHF and Stages (Ref 40)
(BNP based definitions not used, as it is not available in the NT for acute use)

Clinical Presentation	Incidence*	Signs and Symptoms	Characteristics
1. Elevated systolic blood pressure	>50%	Usually develop abruptly	Predominantly pulmonary (radiographic/clinical) rather than systemic congestion due to rapid fluid redistribution from systemic to pulmonary circulation; many patients have preserved EF
2. Normal systolic blood pressure	>40%	Develop gradually (days or weeks) and are associated with significant systemic congestion	Despite high ventricular filling pressure, radiographic pulmonary congestion may be minimal because of pulmonary vasculature/lymphatics adaptation due to chronic elevated left atrial pressures
3. Low systolic blood pressure (90 mm Hg)	<8%	Usually have a low cardiac output with signs of organ hypoperfusion	Many of those patients have advanced or end-stage HF
4. Cardiogenic shock	<1%	Rapid onset	Primarily complicating acute MI, fulminant myocarditis
5. Pulmonary edema	<3%	Rapid or gradual onset	Clinical: severe dyspnea, tachypnea, tachycardia, and hypoxemia, requiring immediate airway intervention Radiographic: present in up to 80% of patients; often not associated with clinical pulmonary edema
6. “Flash” pulmonary edema	?	Abrupt onset	Precipitated by severe systemic hypertension. Uncorrected, respiratory failure and death ensue. Patients are easily treated with vasodilators and diuretics. After blood pressure normalization and reinstitution of routine medications, patients can be discharged within 24 h
7. Isolated right HF	?	Rapid or gradual onset	Not well characterized; there are no epidemiological data (eg, acute cor pulmonale, right ventricular infarct)
8. Acute coronary syndromes (25% of patients have signs/ symptoms of HF)	?	Rapid or gradual onset	Many such patients may have signs and symptoms of HF that resolve after initial therapy or resolution of ischemia
9. Post–cardiac surgery HF	?	Rapid or gradual onset	Occurring in patients with or without previous ventricular dysfunction, often related to worsening diastolic function and volume overload immediately after surgery.

STAGE	Description
A	Patients at high risk for HF but without structural heart disease or symptoms of HF (e.g., patients with hypertension, atherosclerotic disease, diabetes, obesity, and metabolic syndrome or patients using cardiotoxins or with a family history of cardiomyopathy). Such patients have no identified structural or functional abnormalities of the pericardium, myocardium, or cardiac valves and have never shown signs or symptoms of HF.
B	Patients who have developed structural heart disease that is strongly associated with the development of HF (e.g., previous myocardial infarction, LV remodeling including LVH and low EF, or asymptomatic valvular disease) but without signs or symptoms of HF.
C	Patients with structural disease who have current or prior symptoms of HF (e.g., known structural heart disease and shortness of breath and fatigue, reduced exercise tolerance).
D	Patients with refractory HF requiring specialized interventions (e.g., marked symptoms of HF at rest despite maximal medical therapy—those who are recurrently hospitalized or cannot be safely discharged from the hospital without specialized interventions).

APPENDIX B Attributes of Performance Indicators (Ref 32)

Choosing Performance Measures	
Selection Factors	**Considerations**
Adherence to the potential performance measure results in meaningful improvements in clinically important outcomes	Evidence-based trials, strong clinical practice guideline recommendations for (Class I, Level of Evidence: A) or against (Class III, Level of Evidence: A) the measure
Broad sampling from multiple domains associated with the process of medical care (see Figure 1)	Measures should be distributed across the domains of diagnosis, patient education, treatment, patient self-management, and serial monitoring of success of treatment
Attributes of Selected Measures	
Measure Characteristics	**Relevant Attributes**
Useful in improving patient outcomes	Interpretable Actionable
Measure design	Denominator precisely defined
	Numerator precisely defined
	Established types of validity
	• Face
	• Content
	• Construct
	Established reliability
Measure implementation	Feasibility
	• Reasonable effort
	• Reasonable cost
	• Reasonable time period for collection
Overall assessment by Performance Measures Writing Group	Overall assessment of measure by explicit, predefined criteria for inclusion in measurement set

Adapted from Normand SL et al.[2]

APPENDIX C Choosing Performance Indicators (Ref 32)

Choosing Performance Measures	
Selection Factors	New Considerations
Confidence that adherence to a potential performance measure would result in meaningful improvements in clinically important outcomes	The methodology and logic by which a performance measure was selected, with a clear description of anticipated benefits on meaningful clinical outcomes, should be disclosed by the writing committee.
Costs of measure	Explicit demonstration that application of the performance measure to patients is associated with an acceptable ICER.
	An estimate of the societal burden of more complete adherence to the performance measure.
Outcomes measures	The outcomes to be considered must be clinically relevant, including mortality, irreversible morbidity, and health status (symptoms, function, and quality of life), and surrogate outcomes should be avoided.
	Previously published recommendations for publicly reported outcomes should be followed.[22]
	Risk adjustment, with carefully selected clinical variables and explicit consideration of demographic characteristics, must be available to render observations interpretable.
	Where possible the population should represent a disease state rather than a procedure applied to a subset of that population.
Measure Characteristics	New Considerations
Use of exceptions	Exclusions of patients from the denominator of a performance measure are reasonable and should be broadly grouped into • medical • patient • system-based reasons for why the patient was not eligible
No. of measures	To minimize the number of measures, efforts at creating a national consensus, involving all stakeholders, on measures to be used for a specified period of time for accountability, pay for performance, and quality-improvement efforts should be developed.
	Although performance measure writing committees should create a full complement of measures for a disease, the NQF should select only a subset of these for use at any particular time.
	The subset should include measures from multiple dimensions of care to facilitate a more complete assessment of quality.
	Measures should be retired when new evidence questions the association of those measures with clinically meaningful outcomes or performance is so high that there is little room for future improvement.
	Retired measures should be considered for reassessment in future years.
Feasibility of data collection	Data collection should occur prospectively through routine transactions of medical care because retrospective collection of data is not sustainable.
	EMR companies need to create and support export of data using standardized formats so that a greater number of providers can participate in national quality-assessment programs.
	Measures need to be developed in a way that recognizes the longitudinal patient care experience and creates “windows” for capturing performance that are practical and clinically interpretable.
Composite measures	The psychometric properties of these measures, including reliability, accuracy, and predictive validity, should be demonstrated.
	The purpose, intended audience, and scope of a composite measure should be explicitly stated.
	The individual measures used to create a composite measure should be evidence-based and reliable.
	The methodology used for weighting and combining individual measures into a composite performance measure should be transparent and empirically tested.
	Composite performance measure reporting by providers should include a measure of the degree of uncertainty surrounding composite estimates.
Attribution	Accountability is an important opportunity to improve practice.
	It is essential that those held accountable have the processes of care being assessed under their locus of control.
	More methodological work is needed for promotion of the concept of shared accountability for evaluating transitions in care.

EMR indicates electronic medical record; ICER, incremental cost-effectiveness ratio; and NQF, National Quality Forum.

Appendix D Heart Failure Disease Management Scoring System (Ref 33)

Table. Heart Failure Disease Management Scoring Instrument

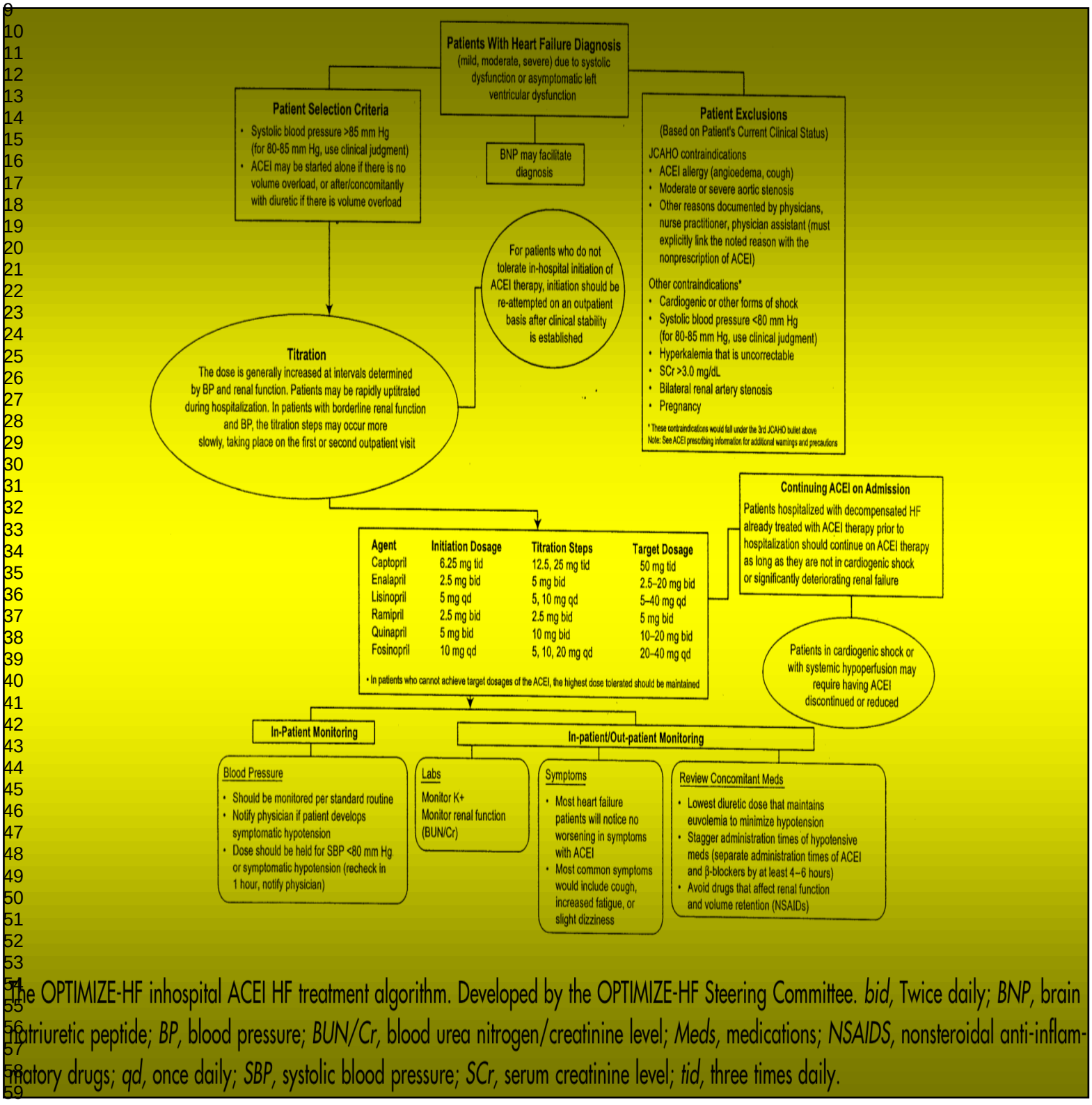
Intervention Category	Points to be Assigned	Comment/Rationale
Recipient	1=Provider alone 2=Patient alone 3=Patient with some inclusion of caregiver 4=Patient with a caregiver who is central to the intervention	Most interventions focus on the patient; yet, coding scheme recognizes that some interventions are aimed at improving provider behavior (eg, system intervention aimed at evidence-based care). Most points are given to interventions that focus on the patient but also include caregivers because an engaged family member act as 2nd set of eyes and memory support, which can deter hospitalization. Thus: 2 points assigned if focus was on patient alone; 3 points if there is some inclusion of the caregiver, 4 points if inclusion of the caregiver was a major component of the intervention.
Intervention content		
Education and counseling aimed at supporting self-care	0=No mention of education 1=Focus solely on importance of treatment adherence 2=Focus on treatment adherence including some creative methods of improving adherence 3=Focus on surveillance but no mention of actions to be taken in response to symptoms (eg, no flexible diuretic management) 4=Emphasis on surveillance, management, and evaluation of symptoms in addition to treatment adherence	Interventions are derived from Krumholz et al,[5] with point allocations assigned to reflect current literature that suggests these interventions are not comparable in efficacy. Individualized patient education and counseling is essential because patients must be engaged in the process of self-care and helped to learn how to make decision about managing their HF. However, true self-care is more than treatment adherence.
Medication management	0=No mention of medication regimen 1=Some mention of medications (eg, importance of medication compliance) but not an active part of the intervention. No attempt to intervene with provider to get patients on an evidence-based medication regimen 2=Evidence-based medication regimen advocated but no follow-up with patient or provider to monitor the suggestion 3=Medication regimen monitored, attempt made to get the patient on evidence-based medications, with follow-up monitoring done with patient or provider	Patients on optimal, evidence-based therapies are significantly less likely to have acute exacerbations and hospital admissions.
Social support Peer support	0=No mention of a peer support intervention 1=Peer support mentioned but not integral to intervention 2=Peer support integral component of intervention	Peer support interventions not used commonly but when used they appear to improve perceived support rather than self-care. Support has been conceptualized as a moderator of the relationship between intervention and outcome.
Surveillance by provider: Remote monitoring	0=No use of remote monitoring or telehealth 1=Remote monitoring is used in conjunction with other interventions that form the main intervention used 2=Telehealth is essential component of intervention	Remote monitoring is distinguished from other methods of communication. Video monitoring may become a common method of communication. For now, remote monitoring is conceptualized as method of engaging patients in process of learning self-care by active engagement.
Delivery personnel	1=Single generalist provider (eg, physician, nurse, pharmacist)	Generalist: Provider specifically noted to not have training in heart failure.
	2=Single HF expert provider (eg, physician, nurse, pharmacist)	Multidisciplinary interventions: Multidisciplinary team involved with all or most patients.
	3=Multidisciplinary intervention	Integrated/choreographed multidisciplinary intervention: Provided by multiple disciplines in collaboration; provided in an HF clinic with policies/protocols specified for HF care.
	4=Multidisciplinary intervention provided in an integrated, choreographed manner	Optimal mix of program delivery personnel is not known, thus assigned points are hypothesized in this study.
Method of communication	1=Mechanized via internet or telephone 2=Person-to-person by telephone 3=Face-to-face, individual, or in a group 4=Combined: Face-to-face at least once alone or in a group with individual telephone calls in between meetings	Most interventions involve combined individual approach with telephone/face-to-face contact. Points should be assigned based on predominant method of communication The method of communication varies widely within individual HF disease management programs, making it difficult to judge how the method influences outcomes. Thus, assigned points are hypothesized in this study.

Table. *Continued*

	Points to be Assigned	Comment/Rationale
Intensity and complexity		Some literature suggests that more intense, complex, and lengthy interventions are associated with better outcomes, though simple interventions have also been effective. Two categories were created to capture this item: Duration and complexity.
Duration	1=≤1 mo 2=≤3 mo 3=≤6 mo 4=>6 mo	
Complexity	1=Low: single contact with little or no follow-up 2=Moderate: >1 but <4 and/or infrequent contact or contacts of short duration 3=High: multiple contacts of significant duration	Complexity is judged on frequency of content and duration of visits/calls. Assigned points are hypothesized in this study.
Environment	1=Hospital: Inpatient only 2=Clinic/outpatient setting 3=Home-based 4=Combination of settings	Krumholz et al[5] note that it is not yet clear which environmental factors are associated with success. Thus assigned points are hypothesized in this study. Many interventions are provided in a more than 1 setting, and scoring endeavors to capture these combinations.

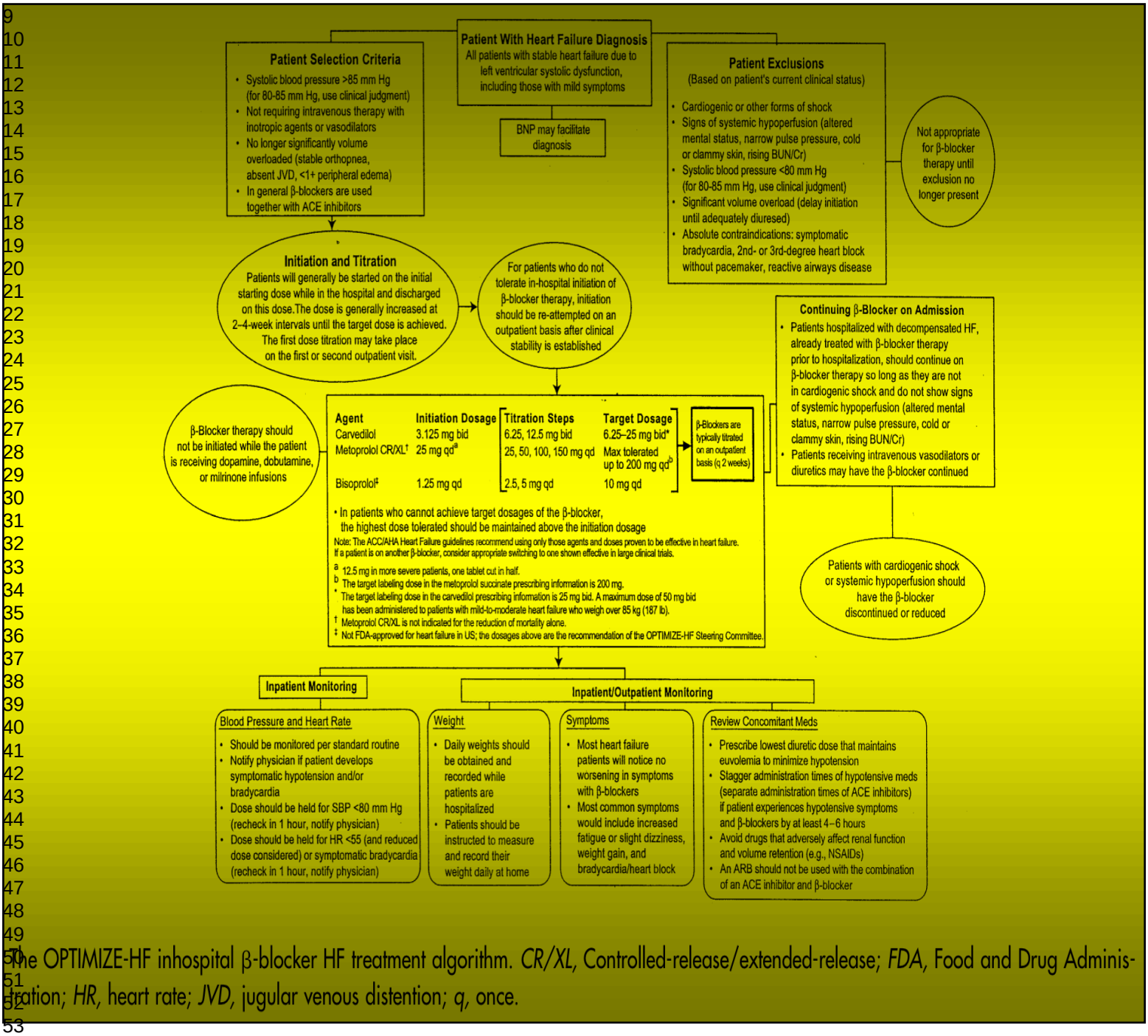
Note: All available sources describing the intervention should be used to ascribe scores.

Appendix E Model of ACE-I Titration in OPTIMIZE-HF (Ref 34)



The OPTIMIZE-HF inhospital ACEI HF treatment algorithm. Developed by the OPTIMIZE-HF Steering Committee. *bid*, Twice daily; *BNP*, brain natriuretic peptide; *BP*, blood pressure; *BUN/Cr*, blood urea nitrogen/creatinine level; *Meds*, medications; *NSAIDS*, nonsteroidal anti-inflammatory drugs; *qd*, once daily; *SBP*, systolic blood pressure; *SCr*, serum creatinine level; *tid*, three times daily.

Appendix F Model of Beta- Blocker Titration in OPTIMIZE-HF (Ref 34)



The OPTIMIZE-HF inhospital β-blocker HF treatment algorithm. *CR/XL*, Controlled-release/extended-release; *FDA*, Food and Drug Administration; *HR*, heart rate; *JVD*, jugular venous distention; *q*, once.

APPENDIX H: The Flinders ProgramTM for Chronic Condition Management Information Paper - SUMMARY (Ref 45)

The Principles of Self-management	**Aim of the Flinders ProgramTM**	**Assessment Tools Goals**
1. Have knowledge of their condition 2. Follow a treatment plan (care plan) agreed with their health professionals 3. Actively share in decision making with health professionals 4. Monitor and manage signs and symptoms of their condition 5. Manage the impact of the condition on their physical, emotional and social life 6. Adopt lifestyles that promote health 7. Have confidence, access and the ability to use support services.	1. Improves the partnership between the client and health professional(s) 2. Collaboratively identifies problems and therefore better (i.e. more successfully) targets interventions 3. Is a motivational process for the client and leads to sustained behaviour change 4. Allows measurement over time and tracks change 5. Has a predictive ability, i.e. improvements in self-management behaviour as measured by the PIH scale, relate to improved health outcomes.	1. Partners in Health Scale 2. Cue and Response interview 3. Problems and Goals Assessment • Identification of Issues • Formation of an individualised Care Plan • Monitoring and reviewing

PIH	**C&R**	**Problem and Goals (P&G) Assessment**
• Knowledge of condition • Knowledge of treatment • Ability to take medication • Ability to share in decisions • Ability to arrange appointments • Ability to attend appointments • Understanding of monitoring and recording • Ability to monitor and record • Understanding of symptom management • Ability to manage symptoms • Ability to manage the physical impact • Ability to manage the social impact • Ability to manage the emotional impact • Progress towards a healthy lifestyle • Ability to know and navigate the health system	• The C&R process uses a series of open-ended questions or cues to explore the patient's responses to the PIH Scale in more depth. E.g. • **Knowledge of Treatment** - What can you tell me about your treatment? - What other treatment options including alternative therapies do you know about? - What does your family/carer understand about your treatment? • **Sharing in Decisions** - Does your doctor/health worker listen to you? - How involved to you feel in making decisions about your health? • **Healthy Lifestyle** - What are you doing to stay healthy as possible? - What things to you do that could make your health	- The Problems and Goals assessment is another tool that can be used as an adjunct to the PIH and C&R process or as a stand-alone assessment. **Notes:** The health worker may well see one of these issues as the main or biggest problem for the client. The client may see the same thing as their biggest problem but they may see something else as having a far greater impact. For example, the clinician might think that the way the client uses their medication is the biggest problem, however the client may think their biggest problem is the demands the family places on them, perhaps they are caring for grandchildren everyday and have little time for themselves. As well as defining the problem from the client's perspective, this assessment also clearly identifies a goal or goals that the client can work towards