



ANMCO/SIC Consensus Document: cardiology networks for outpatient heart failure care

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KEYWORDS

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Outpatient clinics;
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Changing demographics and an increasing burden of multiple chronic comorbidities in Western countries dictate refocusing of heart failure (HF) services from acute in-hospital care to better support the long inter-critical out-of-hospital phases of HF. In Italy, as well as in other countries, needs of the HF population are not adequately addressed by current HF outpatient services, as documented by differences in age, gender, comorbidities and recommended therapies between patients discharged for acute hospitalized HF and those followed-up at HF clinics.

The Italian Working Group on Heart Failure has drafted a guidance document for the organisation of a national HF care network. Aims of the document are to describe tasks and requirements of the different health system points of contact for HF patients, and to define how diagnosis, management and care processes should be documented and shared among health-care professionals.

The document classifies HF outpatient clinics in three groups: (i) community HF clinics, devoted to management of stable patients in strict liaison with primary care, periodic re-evaluation of emerging clinical needs and prompt treatment of impending destabilizations, (ii) hospital HF clinics, that target both new onset and chronic HF patients for diagnostic assessment, treatment planning and early post-discharge follow-up. They act as main referral for general internal medicine units and community clinics, and (iii) advanced HF clinics, directed at patients with severe disease or persistent clinical instability, candidates to advanced treatment options such as heart transplant or mechanical circulatory support. Those different types of HF clinics are integrated in a dedicated network for management of HF patients on a regional basis, according to geographic features. By sharing predefined protocols and communication systems, these HF networks integrate multi-professional providers to ensure continuity of care and patient empowerment.

In conclusion, This guidance document details roles and interactions of cardiology specialists, so as to best exploit the added value of their input in the care of HF patients and is intended to promote a more efficient and effective organization of HF services.

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Introduction

Efficiency and sustainability of health-care systems are based on the ability of professionals to tailor patient care in the context of scientific evidence, making a rational and appropriate use of resources. The epidemiological scenario of Western countries, marked by ageing of the population

and rising multimorbidity and chronicity, mandates a shift from the 'acute care model' to the 'chronic care model' where patients suffering from chronic diseases are effectively managed outside the hospital with the goal of improving their quality of life and ensure their empowerment through education and knowledge of the disease.

The purpose of this document is to outline the characteristics of a national care network for heart failure (HF) patients. The document describes requirements and responsibilities of the different points of contact with the patient, and procedures for recording and sharing processes of diagnosis, treatment and care. Contents are intended to harmonize with the novel hospital standards set by DM 70 02/04/2015 and the National Plan for Chronicity in the Healthcare Agreement 2014-2015.

This document originates from hospital cardiology, the largest share in this medical branch, in order to improve the standards for specialist care, but turns back to it with the understanding that HF management goes beyond the hospital setting. The document acknowledges the need to integrate cardiology in multidisciplinary cooperation with the scientific societies of all other professionals active in the care of HF patients, in the community, in hospitals and in specialist training.

The creation of regional networks based on a nationally shared address is proposed here as the main road to

integrate cardiology specialist approach to multidisciplinary and multi-professional settings in order to take care of HF patients at different stages of the disease in an appropriate and cost-effective manner.

A health services 'Network' is the integration of diagnostic, therapeutic and care activities provided by different professionals and different organizations, in the hospital and in the community, that cooperate to achieve a shared mission.

As other forms of health services network, the HF Network is characterized by the presence of elements ('nodes'), with reciprocal uni- or bi-directional connections, that are governed according to clear predefined rules and agreements and share common objectives.

The objectives of the HF network are the improvement of patients' quality of life, the decrease of hospital admissions and the containment of health-care costs. Therefore, this document is open to dialogue with government bodies and health services administrations, as well as with organizations and health professionals, and patients, public opinion, and society in the broadest sense.

Background

Chronic HF (CHF) is a leading cause of mortality, morbidity, and resource consumption in Western countries.¹⁻⁴ The natural history of CHF is characterized by clinical exacerbations interspersed with periods of clinical stability, leading to progressive deterioration of functional capacity and quality of life.

The role of cardiologist for high-quality care of CHF patients has been well documented in the literature: specialist input is associated with improved survival and reduced readmissions rates, in particular when shared multidisciplinary care pathways are activated.⁵⁻⁸ Dedicated HF clinics may allow prompt intervention through earlier detection of impending destabilization to reinstate euvoemia and thus reduce the readmission rate.

Disease management programmes of the late 90s focused on hospital-based multidisciplinary HF outpatient clinics (HFOCs), staffed by cardiologists and dedicated nurses. However, the diverse structure of European and North American health-care systems, differences in enrolled populations, program components, and professional competences, the inadequate definition of the comparative standard of care and the negative results of many recent trials have cast doubt on program effectiveness and their potential additional costs.⁹

Although during the last decade standards for HFOCs have been defined and the need for careful evaluation of the quality of care they offer has been stressed,¹⁰⁻¹² few studies have assessed the services offered and the characteristics of patients attending these clinics.¹³ Overall, patients followed-up at HF outpatients clinics seems to be 'cream-skimmed' with respect to the typical patient discharged after an acute HF episode: they are younger age, less often female, with fewer comorbidities; many are stable and paucisymptomatic and could be trusted to primary care physicians. The wide variability among clinics as concerns the proportion of new patients recruited, the

frequency of follow-up visits, diagnostic test orders, and availability of telemonitoring tools, appears vastly unrelated to clinical characteristics. Hence homogeneous and standardized care pathways are sorely needed, as well as greater population turn-over, in order to take care of new patients and/or of those who can most benefit from specialist care.

During the last two decades, the Italian Association of Hospital Cardiologists (ANMCO) has pioneered the growth and integration into a pragmatic research network of HFOCs, through observational studies and standardized data collection using a common software in a database where over 22 000 patients had been recruited up to 2015. The subgroup enrolled in the IN-HF outcome registry branch is representative of the most recent Italian cardiology practice,¹⁴ and underscores how CHF patients are highly selected with respect to contemporary acute HF patients admitted to Cardiology or Medicine wards^{14,15} (Table 1).

The mismatch between real-world epidemiology and the current role of HF outpatient clinic management fuels the controversy around the effectiveness of HFOCs in targeting health care needs and their added value in care networks.^{16,17} The open challenge is the field validation of tailored, cost-effective models, that should spread from community care across to intensive tertiary care referral programs, with variable options for telemonitoring, teleconsulting, and patient education. HFOCs should strive for more efficient care pathways by maintaining an appropriate mix between entry of new patients to be assessed or re-evaluated at critical epochs of their disease history, and personalized follow-up controls for patients with advanced unstable disease. We need an efficient organization of care in a HF network to serve with specialist input a wide population of patients, while interfacing cardiologists in a systematic and flexible style with different health-care professionals. In this way, we will be able to adapt care pathways to emerging epidemiological needs and pursue quality of care and appropriate allocation of finite resources.

The network for integrated heart failure care

Functions of the network

The network of heart failure centres fulfils the following functions

- (1) To ensure a clinical care pathway aimed to achieve continuity of care, timeliness of response and flexibility in identifying the appropriate care setting.
- (2) To integrate in-hospital and outpatient cardiologist care with the activities of general practitioners, of other specialists and health and social workers, according to shared pathways with predefined roles and responsibilities of the different actors. Care pathways should identify the most appropriate care in relation to the stage of disease, the severity and the absolute and relative weight of the disease in determining life expectancy and quality of life.
- (3) To define and apply tools useful to evaluate and improve the quality of care, by assessing indicators of

Table 1 Characteristics of patients with acute HF hospitalized in cardiology or medicine wards and CHF patients followed-up in outpatient clinics

	Acute HF		Chronic HF
	INHF outcome (<i>n</i> = 1855)	CONFINE ^a (<i>n</i> = 1411)	INHF outcome (<i>n</i> = 3755)
Age years	72 ± 12	79 ± 10	69 ± 12
Proportion female	40%	52%	24%
Body mass index	28 ± 5	27 ± 5	27 ± 4
Obesity (BMI > 30 kg/m ²)	29%	22%	22%
Hypertension	58%	63%	43%
Chronic kidney dysfunction	32%	44%	21%
COPD	30%	27%	21%
Diabetes	40%	32%	30%
Anaemia	39%	40%	20%
Ischaemic aetiology	42%	44%	46%
Atrial fibrillation	8%	43%	30%
LV ejection fraction%	38 ± 14	43 ± 12	38 ± 11
Pressione sistolica mmHg	134 ± 33	141 ± 27	126 ± 19
Sodium < 136 mEq/l	19%	28%	9%
Creatinine mg/dl	1.2 [1.0-1.6]	1.5 ± 0.9	1.2 [1.0-1.5]
In-hospital mortality	6.4%	4.4%	5.9% ^b
Length of stay	12 ± 10	14 ± 10	—
Beta blockers	65% ^b	31% ^b	79%
ACE inhibitors/ARB	78% ^b	79% ^b	90%
Aldosterone antagonists	59% ^b	32% ^b	38%

ACE, angiotensin converting enzyme; ADHF, acute decompensated heart failure; ARB, angiotensin receptor blockers; BMI, body mass index; COPD, chronic obstructive pulmonary disease; HF, heart failure; INHF, Italian Network on Heart Failure; LV, left ventricular.

^aMedicine wards.

^bOne-year post-discharge.

outcome, process and response to patients' preferences and needs.

- (4) To promote continuous training of all professionals involved in the network.

Construction of the network

Recommendation 1—Define the essential nodes of the network, which should be made available to every patient, in relation to his/her individual characteristics and needs. The nodes are represented by (i) primary care; (ii) out-of-hospital cardiology centres for the care of chronic diseases and HF; (iii) hospital cardiology centres; and (iv) medical-surgical centre with Heart Transplantation and/or Mechanical Circulatory Support Programs.

Recommendation 2—Define catchment areas according to geographical location, population characteristics, availability and quantity of resources that may influence the organization of the offer.

Recommendation 3—Analyse, within each area, the characteristics of services in terms of specialist care provided in and out of the hospital, as well as the organization of primary care. This analysis should define the mode of interaction between general practitioners and the 'proximity cardiology', i.e. the cardiology unit with direct access from the community when appropriate.

Recommendation 4—Identify, within each area, one or more hospitals with ultra-specialistic skills and resources, in order to deal with the diagnostic process and care of complex cases and patients with advanced HF. This

'reference Cardiology' should represent the interface for centres with a heart replacement program.

Recommendation 5—Identify on a national level, the medical-surgical centres with heart replacement programs. For their limited number, the referral area of centres with heart replacement program will necessarily have expanded borders overcrossing areas.

Recommendation 6—Identify and involve centres for rehabilitative care, residential or home palliative care, psychiatric and social services, long-term care as well as other medical specialties.

Recommendation 7—The organizational structure and methods of formal government of the HF network must be defined by all the actors/managers of clinical pathways. Regulatory and control functions pertain to the regional health authorities and strategic directions of health-care providers.

Network architecture

In the HF network, the 'proximity' (secondary referral centres/district hospital) and 'reference' (tertiary referral) centres, as well as the heart replacement program, represent the range of HF specialist cardiology care. The connections between the various nodes over different levels of complexity are necessarily bidirectional hence the HF network architecture is polycentric. Of note, the HF network is intrinsically more complex than the network for acute coronary syndromes, since it has to take care of both acute and chronic phases, throughout the entire spectrum of the clinical history from the diagnosis to the terminal stages of the disease.

Furthermore, the HF network must deal with diverse clinical profiles, from the young patient, in whom heart disease is the main prognostic determinant, to the frail elderly with multiple chronic comorbidities, in whom HF may not represent the strongest predictor of mortality and poor-quality of life.

Within the network, the distribution and type of HF centres will vary according to regional characteristics and geographical distribution of health-care facilities. Care pathways will be identified for inpatients and outpatients depending on such distribution.

Patients' journey within the network

The stages of a patient's journey in the HF network can be summarized as follows

- (1) Entry into the path. This step corresponds to the first diagnosis of HF. Diagnostic classification and initial therapy setup are crucial for the eventual clinical course. In accordance with the recommendations outlined in European and North American Guidelines, a cardiologist should assess all patients with suspected or new diagnosis of HF, even if they are admitted to non-cardiology units or managed in primary care.
- (2) Follow-up setting. Once diagnostic procedures have been completed, the appropriate therapy has been started and educational interventions aimed at patient empowerment delivered, an outpatient follow-up plan must be drafted. Follow-up should be conducted, in most cases, in synergy with community care and general practitioners. Shared clinical documentation is essential for optimizing this synergy. Finally, according to the individual diagnostic-therapeutic plan, the patient's guideline-based personalized pathway is drawn up, shared and approved by the different actors of the network. This plan defines timing of scheduled visits as well as the reasons and modalities for unscheduled ones.
- (3) Switching between HF centres. Within the network, the patient will be entrusted to different types of HF centres or to primary care practitioners, in relation to improvement/stability achieved or to clinical worsening or for supervening frailty. In order to facilitate a coordinated and unified management, a single HF centre, in synergy with the general practitioner, should take care of the patient. Within the HF network, community care will be promoted as much as possible, with the support of hospital cardiology. Innovative ways of cooperating could include teleconsulting or onsite cardiology consultations at primary care group practices, besides direct contact with the patient and his/her general practitioner through telemedicine or remote monitoring services. Stable collaborations among HF centres of different types or with different range of skills are also encouraged in relation to specific issues such as: (i) arrhythmias and implantation and/or monitoring of electrical devices; (ii) haemodynamic and interventional procedures, (iii) HF surgery, (iv)

renal replacement therapy, and (v) mechanical circulation support.

Referral indications based on patients' profiles and centre facilities are described in *Figure 1*.

Organisation of services

Communication systems

Communication is a crucial element in the network. Effective communication strategies foresee:

- (1) online registration of ongoing activities, planned and carried out on the patient, in an electronic medical record which should be accessible by all operators involved, according to predefined arrangements to ensure security and privacy;
- (2) exchange of clinical data and care protocols; and
- (3) identification of a mandatory minimum data set, which allows to share information necessary for patient management, according to the postulate: 'a shared patient, a single shared registration system'.

The main objectives, therefore, should be to

- (1) ensure that all technological supports (toll-free numbers, e-mail, access to databases, access to records, the medical records, the medical reports, the discharge letters, etc.) useful to favour communication between health professionals are made available;
- (2) coordinate the use of patient data in aggregate form to evaluate and improve the quality and performance of care, as well as for research purposes, at least on the regional level; and
- (3) make telematic services accessible to all stakeholders who may become involved, even if only occasionally or for a limited period, in the management of patients with HF, including hospital, emergency services, primary care offices, district, home care services, hospices.

Professional skills and training

It is the responsibility of the authority for health services organization to ensure that the HF network makes use of competent and trained staff. If there are no such professionals in the area, appropriate plans for staff training should be implemented before starting HF centre activity. Moreover, continuous education processes should be in place to ensure up-to-date competence.

Essential skills of the HF network staff include the ability to relation themselves with patients and care-givers, to work in teams, to recognize diagnostic markers of suspect HF, the indicators of clinical worsening and warning signs. If these skills are not present the staff should be adequately trained.

Network management

The management rules of the HF network should be concerted by chiefs of the HF centres, with the coordination of regional health service authorities, and the involvement of all stakeholders. The tasks of HF network governance will be to

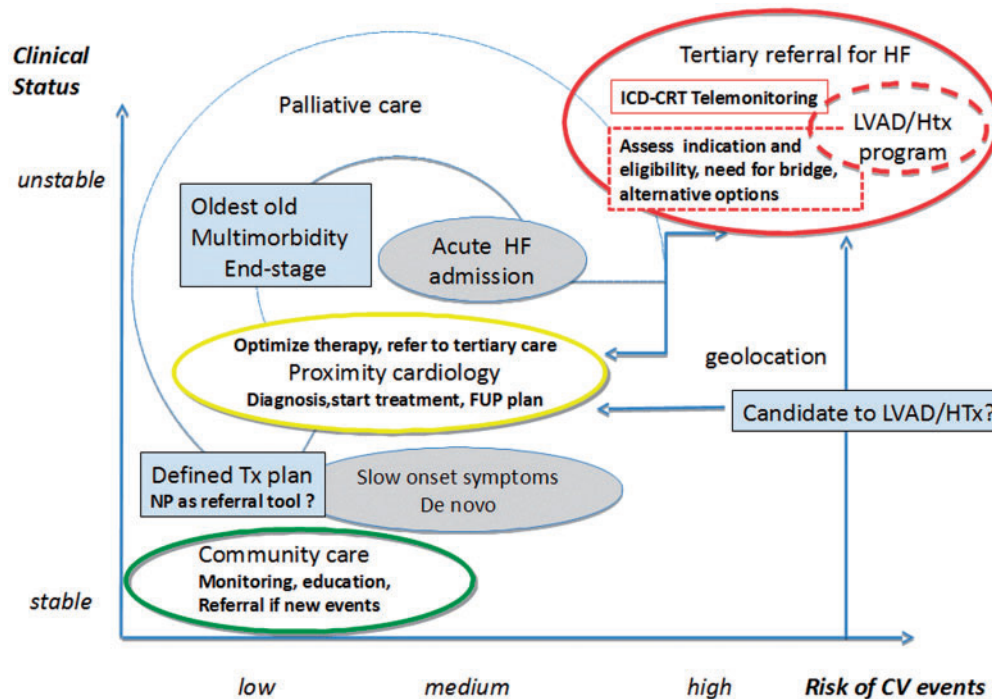


Figure 1 Care referral pathways within the HF network based on patients' clinical profiles. Stable patients at low-to-moderate risk of cardiovascular events, as well as frail elderly subjects with multiple comorbidities, should be managed in the community (green circle), with a focus on clinical monitoring and patient education. Patients with acute exacerbations or *de novo* gradual-onset symptoms should be referred to the geographically nearest (proximity) cardiology using shared protocols based on validated biomarkers. Proximity cardiology units (yellow circles) should admit to hospital patients with acute HF syndromes or outpatients from the community to perform appropriate diagnostic tests, to start or optimize drug therapy and to draft a tailored follow-up plan. Proximity cardiology units should share with network hubs the follow-up care of patients with advanced HF who are candidates to or have received heart transplantation or mechanical circulatory support. Network hubs, based on geographic location, are tertiary referral cardiology units (red circles) that should offer advanced treatment options to unstable patients at high risk of events. All network nodes should entertain close relationships with palliative network nodes for shared care of end-stage HF patients. CRT, cardiac resynchronization therapy; HF, heart failure; HTx, heart transplantation; ICD, implantable cardioverter defibrillator; LVAD, left ventricular assist device; Tx, transplantation.

- (1) promote the definition and implementation of diagnostic and therapeutic plans;
- (2) plan and carry out the reorganization of the functions of hospital and community care in the HF network, and their coordination using minimum structural criteria for dedicated staff, structure type, and control of staff competence. Tasks, responsibilities, resources, methods of communication and patient file sharing should be defined, as well as patient referral criteria across nodes. Furthermore, methods of data collection and analysis to evaluate performance, and commissioning for provision of information flows for clinical audit should be identified;
- (3) define indicators of structure, process and outcome, perceived quality of care and resource use, and activate monitoring by means of clinical audits;
- (4) monitor systematically all components of the network and of the care pathway, with particular attention to the critical issues that may arise in the implementation phase; and
- (5) promote training, cultural development, shared objectives, and communication among all professionals involved, with mutual support and consultation, exchange of diagnostic and

therapeutic protocols, interactive discussion of clinical problems, shared management of complex cases, training events, production of teaching and educational material.

The heart failure management protocol

Regional health service authorities in cooperation with representatives of HF Centres and of the other organizations involved in the network, should prepare a *protocol for diagnosis, treatment, rehabilitation*, the main operational tool of networking which details the most appropriate steps in the delivery of care to HF patients

Although they may differ locally in content and degree of detail, these protocols should generally contain the following points, in accordance with guidelines recommendations:

- Process for HF diagnosis and aetiological research.
- Treatment planning and optimization.
- Identification of precipitating factors for acute exacerbations and/or HF progression.
- Evaluation of risk factors and comorbidities.
- Risk stratification. The use of risk scores designed to assess the severity of the disease and to estimate the probability of adverse events during follow-up is recommended to enable more intensive care for high-risk

patients. Since there is no single perfect model, the score validated in populations most similar to each patient's individual characteristics should be chosen.

- Indications for hospital admission. Clear criteria for hospital admission and in-hospital pathways with regard to the destination ward are essential to optimize care processes and set out diagnostic procedures appropriate to each patient's clinical profile, in particular for the frail disabled elderly.

The following points should be defined:

- *In-hospital treatment according to the clinical profile and therapeutic perspectives.*
- *Follow-up and transitional post-discharge home care.*
- *Criteria for discharge and contents of the discharge summary.*
- *Contents of the outpatient clinical report.*
- *Criteria for cardiac rehabilitation.*
- *Criteria for the activation of home care.*
- *Criteria for the activation of palliative care.*
- *Criteria for interventional/surgical therapies.*
- *Indication, conduction and reporting of the most common diagnostic tests.*
- *Contents of the educational program.*
- *Indications for counselling.*
- *Criteria for the intervention of social services.*
- *Use of telemedicine and/or remote monitoring tools.*

The heart failure outpatient clinic

In order to harmonize patients' pathways within the HF network and ensure transparent provision of care services, it is essential to define the tasks of health-care professionals working in outpatient HF clinics (*Table 2*), the standards for medical record documentation, performance measures for organization structure, process of care and outcomes, and clinical competence of staff (*Table 3*). An overview of the desirable characteristics of HFOCs in the network is presented in *Table 4*.

Activities

The activity of medical staff should include medical visit, assessment of HF-related symptoms and definition of New York Heart Association (NYHA) class, detection of signs related to central and peripheral congestion, evaluation of laboratory data and comorbidities, revision and optimization of pharmacological and non-pharmacological therapy, scheduled laboratory assessment and functional evaluations (e.g. 6-min walking test, cardiopulmonary test), drafting a personalized plan for patient's care.

Nurse staff should participate to patient's care by performing multidimensional evaluation and cooperating in patients' monitoring (e.g. phone follow-up or remote monitoring by implanted cardioverter defibrillator or home sensors), by assessing therapeutic adherence, by empowering patients and relatives with a personalized counselling in order to promote self-management.

Documentation

HF outpatient clinics should record data and information that reflect the adopted protocols and allow clinical management of cases, development of research programs, evaluation, and supervision of clinical activities.

Each HF outpatient clinic should have

- a registry of patients attending the clinic and activities performed
- individual patient records should include: consent to personal data collection; the diagnostic process followed; risk stratification by validated scores; the care plan; the assessment of the efficacy of the adopted treatment; the frequency of scheduled visits; copy of clinical reports transmitted to general practitioners, where information about the patient's diagnostic and therapeutic plan are detailed.

Protocols

HF outpatient clinic should have in place procedures and operating instructions aimed to

- ensure the quality of services declared;
- allow an adequate interaction with primary care and other outpatient clinics within the HF network; and
- standardize the collection of data useful to monitor the indicators for audits and to assess patient-perceived quality.

Quality of care indicators

Organization-oriented indicators

- Time from referral to patient's first visit at the clinic.
- Proportion of patients with clinical reports to primary care physicians.
- Continuous medical education credits earned by the team.
- Compilation of a patient satisfaction questionnaire.

Patient-level indicators

- HF aetiology.
- NYHA class or other functional parameter.
- Signs and symptoms of congestion, vital signs, results of laboratory tests.
- Patient education, including self-care education.
- Quantitative evaluation of left ventricular ejection fraction (LVEF).
- If reduced LVEF and no contraindications:
 - ACE inhibitor/angiotensin receptor antagonist prescribed AND target dose achieved.
 - beta-blocker prescribed AND target dose achieved.
 - mineralocorticoid receptor antagonist prescribed AND target dose achieved.
- If comorbid atrial fibrillation and no contraindications:
 - Oral anticoagulant therapy.
- For eligible patients:
 - Cardioverter defibrillator implantation.
 - cardiac resynchronization therapy.

Table 2 Recommended activities of HF outpatient clinics

Activity domains	Key procedures
Functional evaluation	<ul style="list-style-type: none"> Assess NYHA class at each visit Perform 6-min walking test at baseline and according to clinical course
Quality of life	<ul style="list-style-type: none"> Perform cardiopulmonary test in advanced HF patients and heart transplant candidates Assess using validated questionnaires <ul style="list-style-type: none"> eneric (e.g. SF36, euroQOL). pecific (e.g. Minnesota Living with Heart Failure, Kansas City Cardiomyopathy)
Revision and optimization of medical therapy	<ul style="list-style-type: none"> Prepare a standardized scheme of instructions for all prescribed drugs (indications, common side effects, drug interactions) Register in the clinical record any therapeutic changes and confirm the patient has been properly instructed Check all medicines taken by the patient, including OTC drugs and supplements Check drug intolerances/allergies in order to reassess any stopped or uninitiated treatment Verify adherence to prescribed treatment and investigate causes of poor compliance Establish a procedure to systematically identify eligible patients who do not receive appropriate medications.
Revision and optimization of therapy with devices	<ul style="list-style-type: none"> Establish a procedure to adequately identify patients eligible for device therapy (exclusion of reversible causes of heart failure, appropriate drug titration, careful evaluation of estimated life expectancy) Communication with electrophysiologists for conflicting indications Training in device management in order to detect device malfunction or need for reprogramming; Documentation in the medical record of any variation in device parameters Discussion with the patients of the benefit/risk of electrical therapies
Nutritional evaluation	<ul style="list-style-type: none"> Restriction of sodium and fluid intake to decrease fluid retention and minimize diuretic dose Cooperation with a dietician Sequential recording of weight and body mass index Personalized dietary guidelines according to co-morbidity (e.g. diabetes, obesity, dyslipidaemia, renal failure) Prevention of cardiac cachexia caused by reduced synthesis and/or absorption of nutrients for liver and intestinal congestion
Follow-up schedule	<ul style="list-style-type: none"> Guarantee scheduled or urgent visits Assure early follow-up after discharge from an ADHF admission. Contact high-risk patients within 72 h after discharge from an ADHF admission. Schedule follow-up visits according to needs Plan close follow-up, till proper education of the patient and family and clinical stability have been achieved Schedule monitoring of biochemical or instrumental parameters according to therapy and clinical course
Communication	<ul style="list-style-type: none"> Set up an open and sensitive communication system to allow patients to express their needs and desires Explain potential complications related to the course of the disease and the available treatment options. Investigate potential defects in patient understanding of their clinical status Take into account the discrepancies between individual life expectancy and the estimates of validated scores
Advance directives	<ul style="list-style-type: none"> Investigate the perceptions of patients and family members about disease progression and the choices to be made in the most advanced stages Indicate in the clinical record patient's wishes with respect to cardiopulmonary resuscitation, the possible deactivation of the defibrillator, invasive or surgical procedures, hospitalization Record options in the plan of care and advance directives
Continuous staff training	<ul style="list-style-type: none"> Specific training for nurses (elements of pathophysiology, pharmacology, self-management approach to care, psychosocial issues, quality of life, and palliative care) Specific training for outpatient clinics taking care patients with advanced HF and candidates to heart replacement therapy Promotion of clinical audit
Quality assessment	<ul style="list-style-type: none"> Equipment and personnel adequate for appropriate patient management Implementation of a continuous monitoring system of indicators within the HF outpatient clinic network Electronic sharing of medical records to facilitate audit procedures

ADHF, acute decompensated heart failure; HF, heart failure; NYHA, New York Heart Association; OTC, over the counter.

Table 3 Clinical competencies of medical staff in HFOCs**(A) Community-based HFOCs****Knowledge of:**

- the pathophysiology, differential diagnosis, stages, and natural history of HF
- the typical history and physical examination findings, and their limitations, in the evaluation of HF syndromes
- the indications, contraindications, and clinical pharmacology of drugs used for HF treatment, including adverse effects
- the appropriate pharmacological or non-pharmacological treatment for the prevention of HF in patients with either presymptomatic (stage B) or overt (stage C) HF
- the effects and interactions of HF with other organ systems (kidney, nutritional, metabolic) and in the setting of other systemic disease
- the management of cardiac arrhythmias in HF patients, as well as the indications and risks of ICD, CRT and arrhythmia ablation

Skills:

- to evaluate and manage patients with new-onset and chronic HF
- to use history and physical examination findings to accurately assess volume status and perfusion in HF patients
- to recognize and manage comorbidities in HF patients
- to recognize, manage, and seek appropriate consultation for depression or undue anxiety in HF patients as part of their overall care
- to interpret imaging results in the evaluation of HF patients
- to identify appropriate candidates for palliative care and hospice

Activities

- Identify and address financial, cultural, and social barriers to diagnostic and treatment recommendations
- Utilize an interdisciplinary, coordinated, team approach for patient management, including care transitions and palliative care
- Utilize appropriate care settings and teams for various levels and stages of HF
- Incorporate risk/benefit analysis and cost considerations in diagnostic and treatment decisions
- Effective management of end-of-life issues, including family meetings across the spectrum of patients with HF
- Communicate with and educate patients and families across a broad range of cultural, ethnic, and socioeconomic backgrounds
- Engage in shared-decision making with patients, including options for diagnosis and treatment

(B) Hospital-based HFOCs. In addition to (A)**Skills:**

- to evaluate and manage patients with new-onset, chronic, and acute decompensated HF
- to appropriately obtain and incorporate data from the history, laboratory studies, and imaging modalities in evaluation and management of HF patients
- to select and implement appropriate arrhythmia management, including utilization of ICD, CRT, and ablation of arrhythmias in patients with HF of all aetiologies and severity
- to manage HF patients with complex contributing comorbidities
- to manage refractory HF with temporary MCS
- use of invasive and non-invasive methods of mechanical ventilation
- use of continuous renal replacement therapy (SCUF/CVVH/CVVHD/CVVHDF)

Activities

- Effectively utilize an interdisciplinary approach to monitor HF outpatients to maintain stability and avoid preventable hospitalization

(C) Advanced care HFOCs and HRT programs. In addition to (B)**Knowledge of:**

- the management and diagnostic strategies for populations with HF not due to ischaemic heart disease, including infiltrative and restrictive cardiomyopathies, inherited cardiomyopathies, and those associated with pregnancy and chemotherapy
- the management strategies for highly specialized populations with HF, including those associated with congenital heart disease and chronic pulmonary disease
- the indications, contraindications, and clinical pharmacology for intravenous, vasoactive, and inotropic drugs used for cardiovascular support in advanced/refractory HF
- the indications for referral for HRT
- the types of and indications for MCS
- the indications and clinical rationale for the pharmacological management of patients implanted with MCS
- the clinical pharmacology and use of immunosuppressive medications and other interventions in heart transplant patients in the treatment of acute rejection (*physicians working in heart transplant programs only*)

Skills:

- to evaluate and manage patients with severe HF despite treatment
- to perform invasive haemodynamic monitoring
- to incorporate results of haemodynamic measurements and monitoring to make appropriate management decisions in complex or advanced HF patients of all aetiologies and severity or in patients with MCS
- to interpret and incorporate results of cardiopulmonary exercise testing into management of HF patients, including physical activity and exercise recommendations
- to manage patients with advanced HF and complex arrhythmias, including patients with MCS, in conjunction with clinical cardiac electrophysiologists

(continued)

Table 3 Continued

- to appropriately utilize initial screening studies to determine patient eligibility for HRT of individuals cared for at non-transplant/non-ventricular assist device facilities, in collaboration with individuals working in HRT programs
 - to evaluate, order all appropriate testing, and determine the appropriateness of a patient for cardiac transplant or MCS (*physicians working in HRT programs only*)
 - to evaluate and manage heart transplant/MCS recipients (*physicians working in HRT programs only*)
 - to identify and manage patients who require transition from hospital to home or to a care facility while on infusion of inotropic or vasoactive agents
 - to identify and manage patients who require transition from hospital to home or to a care facility after heart transplant or permanent MCS (*physicians working in HRT programs only*)
- Others
- Identify the financial, social, and emotional barriers to successful outcomes after surgery
 - Clearly and objectively discuss the therapies available for advanced HF, including palliative care, transplant, or MCS
 - Effectively lead and communicate with the interdisciplinary team involved in heart transplant and MCS (*physicians working in HRT programs only*)

Based on the ACC 2015 Core Cardiovascular Training Statement (COCATS 4)¹⁸.

CRT, cardiac resynchronization therapy; HF, heart failure; HFOCs, heart failure outpatient clinics; HRT, heart replacement therapy; ICD, implantable cardioverter defibrillator; MSD, mechanical circulatory support; SCUF, slow continuous ultrafiltration.

Table 4 Structure and organization of HFOCs

Clinic	(A) Community based	(B) Hospital based	(C) Advanced care and HRT ^a programs
Location	Community: <ul style="list-style-type: none"> • Primary care territorial unit, health home, functional territorial aggregation, primary care association • General cardiology outpatients' clinic Hospital: <ul style="list-style-type: none"> • Non-cardiology units (internal medicine, geriatrics, emergency medicine) • Hospitals with emergency services only • Intermediate long-term care units • Cardiac rehabilitation units 	Hospitals with cardiology units: <ul style="list-style-type: none"> • Cardiology inpatient unit <i>and/or</i> <ul style="list-style-type: none"> • CICU <i>and/or</i> <ul style="list-style-type: none"> • Cardiac catheterization laboratory either on site or in a functionally linked centre <i>and/or</i> <ul style="list-style-type: none"> • EP Laboratory either on site or in a functionally linked centre 	Hospitals with a cardiology division: <ul style="list-style-type: none"> • cardiology inpatient unit • CICU • on site cardiac catheterization laboratory open 24 h/day, 7 days/week, with expertise in performing EBM • on site EP Laboratory • cardiac surgery unit • Integrated Cardiac-Surgical HF program
Patient profile	<ul style="list-style-type: none"> • Patients with stable chronic HF^b who <ul style="list-style-type: none"> • have concluded the risk stratification process OR • do not need additional diagnostic/therapeutic procedures or these are ongoing in collaboration with hospital-based clinics 	<ul style="list-style-type: none"> • Patients with newly diagnosed HF who need <ul style="list-style-type: none"> • risk stratification • investigation of the aetiology of HF • Patients with recent decompensation • Patients needing interventional diagnostic or therapeutic procedures 	<ul style="list-style-type: none"> • Patients at high risk of decompensation (severe exercise intolerance and/or severe cardiac dysfunction) • Patients who are taken care of in (B), but need diagnostic and/or therapeutic procedures only available in (C). • Patients needing cardiac surgery • Patients with advanced HF^c HRT programs: as above, but dedicated primarily to: <ul style="list-style-type: none"> • patients with advanced HF who are potential candidates for HRT • heart transplant/MCSD recipients
Requirements	Compliance with regional accreditation standards for outpatient clinics	Compliance with regional accreditation standards for outpatient <i>specialist</i> clinics.	In addition to (B): <ul style="list-style-type: none"> • multidisciplinary team led by HF cardiologists, cardiac

(continued)

Table 4 Continued

Clinic	(A) Community based	(B) Hospital based	(C) Advanced care and HRT ^a programs
		<ul style="list-style-type: none"> • Outpatient clinic dedicated to HF patients • Day-hospital and/or Day-service and/or intensive hospital-based outpatient care • Either on site or functionally linked EP laboratory with expertise in both ablation and pacing, including cardiac resynchronization therapy • Either on site or functionally linked cardiac catheterization laboratory 	<p>surgeons and HF specialist nurses, and including additional health-care professionals as needed</p> <ul style="list-style-type: none"> • the multidisciplinary team is responsible for integration across the HF care continuum <p>Heart transplant/MCSD programs:</p> <ul style="list-style-type: none"> • compliance with current legislation about heart transplant and MCSD centres • active MCSD program (heart transplant programs) • on site availability of the facilities and competencies necessary for the diagnosis and treatment of the potential complications of HRT
Equipment and facilities	<ul style="list-style-type: none"> • Sphygmomanometer • Electrocardiograph • Pulse oximeter • Scales • Defibrillator (<i>desirable</i>) • Cardiac ultrasound scanner: <i>optional but desirable, as it allows objective documentation of cardiac dysfunction and, thus, the diagnosis of HF</i> 	<p>In addition to (A):</p> <ul style="list-style-type: none"> • cardiac ultrasound scanner • defibrillator • dressing and phlebotomy tray <p>On site or in a functionally linked centre</p> <ul style="list-style-type: none"> • Holter monitoring • cardiopulmonary exercise testing • advanced cardiac imaging • equipment for the interrogation of implantable devices • remote device monitoring program 	<p>As in (B) but all the facilities and equipment must be available on site, and in addition:</p> <ul style="list-style-type: none"> • telemetry equipment, allowing also oxygen saturation monitoring by pulse oximeter and non-invasive blood pressure monitoring • nuclear cardiology <p>MCSD programs:</p> <ul style="list-style-type: none"> • equipment for MCSD monitoring
Minimal volume of activity	<ul style="list-style-type: none"> • Time slots and/or days dedicated to HF patients 	<ul style="list-style-type: none"> • At least 2 days/week dedicated to HF patients • Fast track (within 72 h) for unstable patients • Nurse-led telephone follow-up for unstable patients 	<p>In addition to (B):</p> <ul style="list-style-type: none"> • at least 3 days/week dedicated to HF patients <p>HRT programs:</p> <ul style="list-style-type: none"> • telephone consulting 24 h/day, 7 days/week • specialist assistance for emergencies in the hospital 24 h/day, 7 days/week
Staff	<ul style="list-style-type: none"> • At least one physician with expertise in HF • At least one nurse 	<ul style="list-style-type: none"> • At least one HF cardiologist • At least one HF specialist nurse responsible for care integration across the HF spectrum • The involvement, in a multidisciplinary team, of additional medical (internists, geriatricians, nephrologists, etc.) and non-medical (psychologists, nutritionists, dietitians, physiotherapists) professionals is desirable 	<ul style="list-style-type: none"> • At least three HF cardiologists • HF specialist nurses • Cardiac surgeons with expertise in the surgical treatment of HF <p>Multidisciplinary team MCSD programs:</p> <ul style="list-style-type: none"> • nurses and cardiac surgeons with expertise in the management of MCSD recipients^d; this is desirable for all Advanced care clinics, so that they can participate in the follow-up of MCSD recipients

(continued)

Table 4 Continued

Clinic	(A) Community based	(B) Hospital based	(C) Advanced care and HRT ^a programs
Services	<ul style="list-style-type: none"> • Referral of patients newly diagnosed with HF to hospital clinics, if the aetiology is unclear • Implementation of guideline-directed medical therapy, assessment of clinical stability and referral to hospital-based clinics where appropriate • Support to institutions or home care services for frail patients • Integration with palliative care services 	<p>In addition to (A):</p> <ul style="list-style-type: none"> • timely consultation for confirmation of HF diagnosis, risk stratification, implementation of guideline-directed therapy, referral to advanced care clinics/HRT programs when appropriate • referral of stable patients at low-risk of events to community-based clinics, according to predefined protocols • support to institutions/home-care services for frail/end-stage patients by means of telemonitoring development of collaborative clinical pathways with the ER, and internal medicine and cardiology units, that describe appropriateness criteria for admission to the CICU, transfer to a regular floor/intermediate care unit, referral to palliative care services, admission of low-risk patients to the ER observation unit with subsequent follow-up in the HF clinic • patient self-care education, including the preparation of educational material for patients and care givers • continuous education of health-care professional working in the hospital and in the community 	<p>Heart transplant programs:</p> <ul style="list-style-type: none"> • nurses with expertise in the management of heart transplant recipients <p>In addition to (B):</p> <ul style="list-style-type: none"> • referral of stable patients at low risk for hospitalization to Community-based clinics, according to defined protocols • referral of potential candidates for HRT to HRT programs • follow-up of MCSHD recipients <p>HRT programs:</p> <ul style="list-style-type: none"> • assessment of patient eligibility for heart transplant or MCSHD <p>Heart transplant programs:</p> <ul style="list-style-type: none"> • management of patients on the transplant waiting list and of transplant recipients <p>MCSHD programs:</p> <ul style="list-style-type: none"> • continuous education of MCSHD recipients and community health-care professional involved in the care of these patients • evaluation of the quality of life before and after MCSHD implant by means of validated questionnaires

CICU, cardiac intensive care unit; CVVH, continuous veno-venous hemofiltration; CVVHD, continuous veno-venous hemodialysis; CVVHDF, continuous veno-venous hemodiafiltration; EP, electrophysiology; HF, heart failure; HRT, heart replacement therapy; EBM, endomyocardial biopsy; MCSHD, mechanical circulatory support devices.

^aHRT: heart transplant, implant of durable mechanical circulatory support devices.

^bStable chronic HF is defined as:

- stable symptoms on oral therapy for at least 15 days;
- stable dose of diuretics for at least 15 days;
- no signs of congestion (peripheral oedema, rales, jugular veins distension);
- no symptomatic hypotension.

^cIn accordance with the 2007 position statement from the Heart Failure Association of the European Society of Cardiology¹⁹, Advanced HF is defined as:

- NYHA functional class III-IV symptoms;
- episodes of fluid retention and/or of reduced cardiac output at rest;
- objective evidence of severe cardiac dysfunction;
- severe impairment of functional capacity;
- history of ≥ 1 HF hospitalisation in the past 6 months;
- presence of all the previous features despite attempts to optimize therapy, including CRT, when indicated.

^dSee Table 3 for detailed staff competencies required.

Outcome indicators

- Number of all-cause, cardiovascular, and HF readmissions at 1, 3, and 12 months.
- Mortality rate at 1 year.
- Quality of life.

Conclusions

Heart failure is a complex disease that generates an enormous burden to health-care systems. Ageing increasing multimorbidity and an expanding array of costly advanced-technology therapeutic options further impact on the challenges of caring for these patients. The shift from acute to chronic care mandates a proactive role of health-care professionals in building efficient network system and chaperone HF patients through them.

This guidance document details roles and interactions among cardiologists, so as to best exploit the added value of specialist input in the care of HF patients and is expected to promote a more efficient and effective organization of HF.

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