OFFICE IC AR National Heart Failure Registry

INTRODUCTION AND OBJECTIVES

Chronic heart failure affects approximately 2-3% of the general population, but more than 10% of people older than 70 years. It is the final common pathway of most heart diseases not treated adequately, (1-3) and a medical condition that affects prognosis and places a significant burden on the health system. Related morbidity and mortality is high and increases with age. (4,5) Hospitalization periods represent only a small, albeit important, fraction of the patient's life, because it corresponds to the most serious and life-threatening stages. Registries of acute decompensated heart failure have been carried out in different countries and contexts. (6-10) From an economic point of view, hospitalizations determine most of direct and indirect costs. However, most of the patient's life is spent on an outpatient basis, so daily behavior, adherence to recommended standards, rapid access to health care services and adequate physician work are the most responsible determinants of evolution when it comes to preventing hospitalizations.

Knowing the different contemporary patterns of chronic ambulatory heart failure, the diagnostic methods and treatments, patient prognosis, and the barriers that stand in the way of the best treatment, is the first necessary step to improve the clinical course of the disease and make right decisions in relation to the allocation of resources.

Different chronic heart failure registries have been published around the world, but it is clear that local realities differ. (11) The latest Chronic Heart Failure Registries in Argentina were made 6 to 9 years ago. None of them has been truly representative of the Argentine reality, since the geographical area covered by the two main scientific societies (the Argentine Society of Cardiology, SAC and the Argentine Federation of Cardiology, FAC, each one responsible for one of them) is different. (12,13)

In recent years guidelines have changed and new treatments are in use. Our purpose is to describe adherence to local and international guidelines and define the reasons for non-adherence. (14-17)

METHODS

Participants:

- **Physicians:** cardiologists divided equally between both SAC and FAC Scientific Societies, selected from the registries of both institutions, in a number proportional to the population of each province. Physicians' age, gender, year of graduation, specialty and point of care data will be collected.

  Each physician will provide data on 7 to 10 outpatients (see below) completing an individual file for each of them.

- **Patients**, with a history of chronic heart failure diagnosed by the presence of signs, symptoms and identification of structural or functional heart abnormality through some study (preferably, but not exclusively, echocardiogram, or possibly ECG, laboratory, etc.), with at least 6-month evolution, followed up by the same physicians for at least 3 visits, and free from hospitalization for heart failure in at least the last 3 months.

  Patients must sign an informed consent before being included in the Registry.

  Data on gender, age, geographical area, socioeconomic and educational status, medical coverage, medical history (heart failure, other relevant cardiovascular and non-cardiovascular diseases), physical examination, ECG, chest X-ray, laboratory tests, echocardiogram and other complementary studies, etiology, and pharmacological and non-pharmacological treatment will be collected (see file and instructions).

  Special emphasis will be placed on questioning the reasons why patients are not subjected to certain studies or do not receive a certain treatment recommended by the guidelines in specific situations or conditions. It will also be possible to define the presence of indications outside the guidelines.

  Patients will be followed up in person or by telephone contact every 6 months until completing at least 1 year of follow-up since inclusion, recording data on death, hospitalization due to heart failure or other causes.

Objectives

Primary

To describe a broad and comprehensive picture of chronic heart failure in Argentina, including patients' characteristics, use of diagnostic and therapeutic resources, adherence to practice guidelines, and prognosis.

Secondary

To describe use of diagnostic and therapeutic resource patterns according to baseline characteristics of patients and physicians.

To define mid-term (6 months) and long-term (at least 1 year) prognosis, according to baseline characteristics of patients and physicians.

Methodology

a) Selection of cardiologists equally distributed between SAC and FAC in proportional numbers to the population of each province and CABA

b) Data will be collected on an electronic platform to which the participating physicians will access via a password provided to them.

c) Data transferred to a centralized database will be verified and analyzed in accordance with the objectives of the protocol.

d) The leaders of each district of each Scientific Society will be in charge of coordinating the actions of the physicians in their district and of maintaining initial contact with them.

e) Members of the Heart Failure Councils of both Cardiological Societies will be in charge of periodic folloe-up and control of individual registry completeness.

Statistical analysis

Quantitative variables will be presented as mean and standard deviation or median and interquartile range. Means will be compared using Student's t test or ANOVA, and medians with the Wilcoxon or Kruskal Wallis tests. Qualitative variables will be presented as percentages and will be compared with the chi square test or Fisher test.

The association of predictive variables with the dependent variable will be expressed with odds ratio (OR) and its corresponding 95% confidence interval (95% CI). Event-free survival will be analyzed with a Cox proportional hazards model, and the association of each variable with the outcome will be expressed as hazard ratio (HR) with its corresponding 95% CI. In all cases, the independent association of each variable with the dependent variable will be explored by multivariate analysis.

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INSTRUCTIONS
Variables to consider
Personal data

1. **Code**: it consists of three 2-digit consecutive numbers: the one corresponding to the district number within the society, that of the physician within the district and the correlative number corresponding to the patient (for each physician between a minimum of 7 and a maximum of 10).

2. **Initials**: of the first name and first surname if this were a double surname (thus, there are 2 initials per patient)

3. **Dates** of visit, birth and follow-up: two numbers for day and month, four for year

4. Endemic Chagas zone: it refers to the zone where the patient lives or has lived

5. **Educational level**: illiterate if he/she does not read and write. The maximum educational status is considered, even if it has not been completed

6. **Worker**: usually performed activity. Unemployed: if that condition has been maintained for at least the last 2 months
7. **Properties**: if the patient owns one or both described goods
8. **Medical coverage**: it is considered Private if the patient covers health costs personally, with no medical coverage. None: includes the patient who having no medical coverage is unable to cover the costs of medications, etc.

Cardiovascular history
9. **Smoking**: is considered yes, when the patient is currently a smoker; no, when he he/she has never smoked regularly and ex, id he/she has quitted smoking for at least 1 year
10. **Diabetes**: when fasting blood sugar >126 mg/dL, oral glucose tolerance test >200 mg/dL at 2 hours or glycated hemoglobin >6.4%, or glucose-lowering treatment established for that diagnosis
11. **Hypertension**: when SBP>140 mmHg and/or DBP >90 mmHg, or pharmacological treatment established for that diagnosis
12. **Coronary heart disease history** of angina. AMI, angioplasty or surgery
13. **Valve disease history**: Data is collected only on moderate to more severe valve diseases, with severity diagnosed by complementary methods, or hemodynamic or clinical involvement. More than one may be marked
14. **Valvular surgery**: history of valve repair or mechanical or biological valve replacement
15. **Peripheral artery disease**: of neck or lower limb vessels, clinically evidenced by imaging studies or history of angioplasty or surgery.

Non-cardiovascular history
16. **Stroke, TIA, dementia or depression**: history of diagnosis made by neurologist or psychiatrist
17. **Thyroid dysfunction**: laboratory-confirmed diagnosis, with substitution treatment in case of hypothyroidism or use of ant-thyroid drugs in case of hyperthyroidism
18. **COPD, asthma**: spirometry-confirmed diagnosis, or use of specific drugs for its treatment (bronchodilators, etc.)
19. **Kidney failure**: defined by creatinine clearance <60 mL/min
20. **Cancer, chemotherapy**: current or past.

Heart failure
21. **Usual functional class**: according to NYHA
22. **Evolution time**: in months since initial diagnosis
23. **Prior hospitalization for HF**: since the diagnosis, at any time during the evolution.

Number of hospitalizations
It refers to the last 12 months, due to heart failure, other cardiovascular causes (excluding those due to programmed procedures), or non-cardiovascular causes (excluding those due to programmed procedures). In all cases, a zero should be put if there has been none.

Physical examination
24. **Blood pressure**: in mmHg
25. **Heart rate**: in beats/minute
26. **Congestion**: when on admission at least two of the following signs are recorded: rales, jugular engorgement without collapse or with partial inspiratory collapse, edemas, hepatomegaly, positive hepatojugular reflux, third heart sound.
27. **Hypoperfusion**: when on admission two of the following signs are recorded: symptomatic arterial hypotension, palleness, piloerection, obnubilation, coldness, cyanosis.
28. **Weight**: in kg
29. **Height**: in m

ECG: must be from the las 12 months
30. **Rhythm**: sinus, AF, atrial flutter. If rhythm is given by a pacemaker but there is underlying AF or atrial flutter, indicate both conditions
31. **PR and QRS width**: in ms
32. **Pathological Q**: when it is present in at least 2 contiguous leads, with at least 40 ms width, and amplitude ≥40% of the following R
33. **Left ventricular hypertrophy**: if Sokolow index ≥35 mm, or other characteristic ECG sign
34. **Conduction disorders**: Right and left bundle branch block in the presence of characteristic pattern, with QRS width ≥120 msec. If the right bundle branch block coexists with left anterior hemiblock, indicate both conditions.

Chest X-ray:
From the last 6 months. It is not essential to have a chest X-ray, as only its rate of use in ambulatory practice is tried to be assessed.

Laboratory:
Must be from the last 6 months. Report available data. Each assessment value should be completed with the corresponding unit. Non-available measurements should be reported as NO. In the specific case of Chagas serology, clarify if it was not performed, or having been performed, whether it was negative or positive by one or two tests.

Echocardiogram:

Report the last available one. In case of hospital admission, the one performed during hospitalization should not be considered.

35. **LV function**: preserved, mild, moderate or severe impairment: when functional assessment is qualitative and no EF data is available
36. **Segmental disorders**: present or absent
37. L**eft atrial dilation**: if reported as such, or as diameter >40 mm or surface >20 cm2.
38. **Left ventricular hypertrophy**: if reported as such, or if the septum and posterior wall measure more than 11 mm, or if left ventricular mass is above the reference value
39. **Diastolic dysfunction**: Mild if reported as such, or as E/A ratio <1 or as abnormal relaxation or prolonged relaxation; moderate, if reported as such, or as E/A ratio 1-2 or as pseudonormal pattern; and severe if reported as such, or as E/A ratio >2 or as restrictive pattern
40. **Shortening fraction and ejection fraction**

Other studies performed in the last 2 years:

Answer yes or no to each option. Answer if there is a study conclusively confirming or excluding the presence of coronary heart disease, even though its data is over 2 years old.

Etiological diagnosis

Two options can be marked, but it is strongly suggested to choose only one.

41. **Ischemic**: in case of confirmed history of coronary heart disease, clinically and from complementary studies
42. **Hypertensive**: in case of history of hypertension
43. **Valvular**: in case of moderate to severe valve disease
44. **Chagas**: confirmed by serology and in the presence of ECG and echocardiographic data suggestive of cardiomyopathy of that origin
45. **Idiopathic**: in dilated cardiomyopathy in the absence of coronary heart disease or the other etiologies described
46. **Noncompacted**: in the presence of sufficient amount of noncompacted myocardium to justify ventricular dysfunction. The sole presence of noncompacted myocardium in the echocardiogram is not enough to accept its etiological role
47. **Myocarditis**: in the case of history of suggestive clinical condition, and laboratory data or complementary methods that confirm it
48. **Alcoholic**: in dilated cardiomyopathy, with history of alcohol consumption >10 g daily or reversion of the condition with abstinence
49. **Tachycardiomyopathy**: in dilated cardiomyopathy, with sinus or supraventricular rhythm and persistently elevated heart rate, which is interpreted as cause and not consequence of heart failure
50. **Chemotherapy**: history of antineoplastic treatment considered responsible for ventricular dysfunction, especially anthracyclines and trastuzumab
51. **Amyloidosis**: in the presence of demonstrated cardiac amyloidosis by biopsy or complementary methods
52. **Restrictive cardiomyopathy**: echocardiographic or hemodynamic diagnosis
53. **Hypertrophic cardiomyopathy**: echocardiographic diagnosis
54. **Non-filed**: heart failure of undiagnosed cause
55. **Other**

Treatment

56. **Low-sodium diet**: indication of restricted sodium intake
57. **Physical activity**: supervised if indicated to be performed in a gym or institution under medical control, non-supervised, if indicated to be performed individually and without medical control (includes advice to walk at least 150 minutes daily)
58. **Weight control**: if indicated, it should be done at least once a week
59. **Pharmacological treatment**: mark each drug with either yes or no, and indicate the dose in the cases it corresponds
60. **Pacemake**r: it should be considered that two or more options can coexist when referring to the same device; for example, two-chamber pacemaker, resynchronization therapy and cardioverter defibrillator.

Reasons for no indication or use of resources

It should be taken into account that the questions on the topic do not imply value judgement: the non-use of certain diagnostic or therapeutic resource may have clear justification, or not exist in the opinion of the treating physician clear indication for its use. Thus, it is expected that each question is answered with the utmost precision, with an option in each case to point out reasons not considered in the questionnaire.

61. **Peptides and troponins**: differentiate between no indication, indication but lack of availability of the resource, and indication, with availability but lack of medical coverage.
62. **Chagas serology**: differentiate between not having performed it for not considering the etiological diagnosis plausible (diagnosis prior to Chagas cardiomyopathy, absence of epidemiological environment, preserved ejection fraction, absence of suspicion or presence of alternative diagnosis), or consider it necessary buy without availability
63. **Echocardiogram**: differentiate between no indication for considering unnecessary knowing the ventricular function in the patient to install adequate treatment, no indication for knowing the ventricular function by another method and indication but with difficulty in the implementation
64. **ACEI, angiotensin antagonists, betablockers and aldosterone antagonists**: differentiate between having indi-

cated them and having suspended treatment for some reason, not having indicated them for considering there is contraindication, and not having indicated them for considering that the indication does not apply to the patient. In all cases, an open option is added to the most usual reasons to explain the cause of the suspension or the contraindication.

65. **Anticoagulation in AF**: differentiate between considering it not indicated in the patient, or considering it indicated but unable to carry it out due to difficulty in the control, understand that there is high bleeding risk, economic difficulties or other reasons that might explain the open option

66. **Electrical therapy**: for each device differentiate between not considering its indication in the patient, considering that it is indicated but goes against the patient's refusal or there are difficulties with the medical coverage.

Follow-up
Every 6 months until at least 12 months since inclusion in the study.

Define whether the contact is personal or by telephone. Define whether there has been hospitalization for heart failure or another cause and whether the patient has died. In the latter case, try to characterize the cause of death (if not possible, indicate non-filed) and the date.

PHYSICIAN FILE
PERSONAL DATA
SAC   FAC
Code (**district+physician**): - - / - - /
Name and Surname initials:
Address: ....Locality: ....Province.: ....
Phone: ....
Sex: Male   Female
Date of birth: -- /-- /----
Graduation year: _ _ _ _
Specialty: Internal Medicine   Cardiology   Heart Failure   Other
Did you do a medical residency Yes   No
You develop your activity in: Private office   Institutional office   Both
If you develop your activity in a center, does it have residency?   Yes   No
Are you guided by guidelines and/or consensuses in the diagnosis and treatment of patients with heart failure?   Yes   No
If the answer is yes, which?   ACC/AHA   European   Local guidelines   Other

PATIENT FILE
Current Visit Date: -- /-- /----
PERSONAL DATA
SAC   FAC
Códe (**district+physician+patient**): - - / - - / - -
Name and Surname initials:
Address: ....Locality: ....Province: ....
Phone: ....
Sex: Male   Female
Date of birth: -- /-- /----
Chagas endemic zone   yes   no   doesn't know
Maximum educational level: Illiterate Primary Secondary Tertiary
Worker: Unemployed   Active   Social Plan
Retired/Pensioner   Housewife
Properties: House   Car   Both   None of the two
Medical Coverage:
Private   Social Security   Prepaid   PAMI   Provincial   PROFE   None
1. Personal history
a) cardiovascular
Smoking   yes   no   ex   Diabetes   no   I   II   HTN   yes   no
Chest pain   yes   no   Prior infarct   yes   no
Coronary angioplasry   yes   no   Myocardial revascularization surgery   yes   no
Moderate-severe valve disease   current   no   yes
                        Which?   Ao Stenosis   Ao Regurg   Miit Stenosis   Mitral Regurg
Valvular Surgery   yes   no
Peripheral arteriopathy   yes   no   Stroke/TIA   yes   no

b) non cardiovascular
Dementia   yes   no   Depression   yes   no
Thyroid dysfunction   no   hypo   hyper
COPD-asthma   yes   no   Creatinine> 1.5 mg/dl or KF   yes   no   Dialysis   yes   no
Cancer   yes   no   Chemotherapy   yes   no

c) Heart failure
Usual FC   I   II   III   IV   Evolution time (months)
Prior hospitalization for heart failure   yes   no
d) Number of hospitalizations in the last 12 months
For heart failure   Another CV cause   Non-CV cause

2. Physical examination, ECG, chest X-ray
BP…..../......   HR……….   Congestion   yes   no   Hypoperfusion   yes   no
Weight ….   Height ……
Last ECG (date)……/……/…….
Rhythm: sinus   AF   A flutter   Pacemaker
PR (ms)   QRS width (ms)   Pathological Q   yes   no   LVH   yes   no
LBBB   yes   no   RBBB   yes   no   LAHB   yes   no
Chest X-ray   yes   no   W/H ratio ≥ 0.50   yes   no

3. Last laboratory (date………/……/……)
Hematocrit   Hb (g %)   WBC (per mm3)   Plasma glucose (mg%)
Urea (mg%)   Creatinine (mg%) Sodium (meq/l)   Potassium (meq/l)
Uric acid (mg%)   Cholesterol (mg%)Albumin (g/%)   Total bilirubin (mg%)
NT proBNP (pg/ml)   BNP (pg/ml)   Troponin T or I (mU/l)
Serology for Chagas   not performed   negative   1 test positive   2 tests positive

4. Echocardiogram
Echocardiogram   yes   no   Date of the last echocardiogram
Function   Preserved   Mild   moderate   severe impairment
Segmental disorders   yes   no   LA dilation   yes   no   Hypertrophy   yes   no
Diastolic dysfunction   not assessed   mild   moderate   severe
Shortening fraction (%)   Ejection fraction (%)

5. Other studies in the last two years
Echo stress   yes   no   Perfusion   Thalium- MIBI   yes   no
GXT   yes   no   6-minute walk   yes   no
O2 consumption   yes   no   Holter   yes   no   Magnetic Resonance
Angio CT   yes   no   CTA   yes   no   Endomyocardial biopsy yes   no

¿Does the patient have a study (regardless of the date) confirming or ruling out coronary heart disease?   Yes   no   Which?

6. Etiological diagnosis:
Ischemic   HTN   Valvular   Chagas   Idiopathic   Non- compacted
Myocarditis   Alcoholic   Tachycardiomyopathy   Chemotherapy
Amyloidosis   Restrictive cardiomyopathy Hypertrophic cardiomyopathy   Other   Non-filed

7. Treatment
a) General measures
Low-sodium diet: general indication   specific indication   not indicated
Physical activity: supervised   non-supervised   not indicated
Weight control indications: yes   no
b) Usual pharmacological treatment

Drug	Yes	No	Dose/day (mg)	Drug	Yes	No	Dose/day (mg)
Furosemide				Hydralazine			
Thiazide				Nitrites			
Spironolactone				Amiodarone			
Eplerenone				Ivabradine			
Amiloride				Aspirin			
Digitalis				Thienopyridine			
ACEI (which?)				Statins (which?)			
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ARBs (which?)				OHA (which)			
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Beta blockers (which?)				Calcium antag. (which)			
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Sacubitril-VTN				Sildenafil			
Levothyroxine				Trimetazidine			
Insulin				Allopurinol			
Erythropoietin				NSAIDs			
Oral iron				Oral potassium			
Anxiolytics				Antidepresants			
Corticoids				Non-amiodarone AA			

Flu vaccine   yes   no   Pneumococcal vaccine   yes   no
Oral anticoagulation: acenocoumarol   warfarin
dabigatran   apixaban   rivaroxaban   no
c) Electrical therapy
Pacemaker: yes   no
Which?: Single chamber   yes   no   Dual chamber   yes   no   Resynchronization therapy   yes   no   Defibrillator   yes   no

8. Reasons for no indication or use of diagnosis or treatment resources
a) **If your patient does NOT have natriuretic peptide or troponin assessments, this is due to**:

	Natriuretic peptides	Troponin
It is not considered necessary		
It is considered necessary but there is no availability		
It is considered necessary but it is not acknowledged by the medical coverage		

b) **If your patient does NOT have Chagas serology, this is due to**:
Considers that it is not necessary, due to:
Prior diagnosis of Chagas cardiomyopathy   absence of epidemiological environment
Preserved ejection fraction   absence of other suspicion criteria
Presence of an alternative diagnosis
Considers it is necessary but there is no availability
Another reason

c) **If your patient does NOT have an echocardiogram, this is due to**:
No availability or difficult access
Has ventricular function assessment by another method
Does not consider knowing the ventricular function necessary   Other

d) **If your patient does NOT receive ACEI or ARBs**:
Indicated and had to be suspended   Contraindication Considers that there is no indication
In any of the first two cases, the cause was:
Hypotension   yes no   Kidney dysfunction yes   no Cough yes no   Other, which?..........

e) **If your patient does NOT receive betablockers**:
Indicated and had to be suspended   Contraindication   Considers that there is no indication
In any of the first two cases, the cause was:
Hypotension   yes   no   Bradycardia   yes   no
Conduction disorders   yes   no   HF progression   yes   no   Other, which?...........

f) **If your patient does NOT receive spironolactone-eplerenone**:
Indicated and had to be suspended   Contraindication   Considers that there is no indication
In any of the first two cases, the cause was:
Kidney dysfunction   yes   no   Hyperkalemia   yes   no   Gynecomastia yes   no   Other, which?

g) **If your patient does NOT receive sacubitril valsartan**:
Indicated and had to be suspended   Contraindication   Considers that there is no indication
Indicated but has difficulties with the medical coverage
In any of the first two cases, the cause was:
Hypotension   yes   no   Kidney dysfunction   yes   no   Angioedema   yes   no

f) **If your patient ha AF and is NOT anticoagulated, this is due to**:
Considers it is not necessary   Difficult implementation
Considers a high bleeding risk   Economic difficulty   Other, which?

g) **If your patient does NOT have an ICD , the cause is**:
Considers there is no indication   Indicated but has difficulties with medical coverage
Patient refusal   Other, which?

h) **If your patient does NOT have resynchronization therapy, the cause is**:
Considers there is no indication   Indicated but has difficulties with medical coverage
Patient refusal   Other, which?

9. **Follow-up**
a) 6 months
Date   Personal contact   Telephone contact
Hospitalization for heart failure   yes   no   Date
Hospitalization for another cause   yes   no   Date
Death   yes   no   Date
Sudden   HF progression   Another CV cause   Non-CV cause   Non-filed cause

b) 12 months
Date   Personal contact   Telephone contact
Hospitalization for heart failure   yes   no   Date
Hospitalization for another cause   yes   no   Date
Death   yes   no   Date
Sudden   HF progression   Another CV cause   Non-CV cause   Non-filed cause

c) 18 months
Date   Personal contact   Telephone contact
Hospitalization for heart failure   yes   no   Date
Hospitalization for another cause   yes   no   Date
Death   yes   no   Date
Sudden   HF progression   Another CV cause   Non-CV cause   Non-filed cause

d) 24 months
Date   Personal contact   Telephone contact
Hospitalization for heart failure   yes   no   Date
Hospitalization for another cause   yes   no   Date
Death   yes   no   Date
Sudden   HF progression   Another CV cause   Non-CV cause   Non-filed cause