

The value of the Heart Failure registries

**Presentation of a concept for
an ESC Heart Failure registry**

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Disclosures

None

Aldo P Maggioni is serving as chairman of the Pilot and Long-Term HF registry of the ESC *EurObservational* Research Programme

Why an European registry on HF ?

General argumentations-1

- Increased surveillance of CV disease and its components
- Facilitate interoperability of health data within and across countries
- Monitor standards of care and assess trends
- Benchmark: enable comparison of data on a national and an international level

General argumentations-2

- Promote best practices, including medical devices surveillance
- Optimize health care resources
- Optimize allocation of funds of research to identified priorities

Specific argumentations for HF

- High burden of mortality and hospitalizations, reduced quality of life and increasing healthcare costs
- Registries and surveys generally conducted in:
 - patients with either chronic or acute HF
 - single centre or in a single country

Specific argumentations for HF

- Changes in clinical conditions and in the management strategies generally not available
- Need for a registry able
 - to capture all relevant clinical information, including acute episodes of decompensation
 - to answer specific clinical questions generally not addressed by clinical trials
 - to identify unmet clinical needs

General concerns regarding observational studies

- Consecutiveness
- Representativeness
- Completeness of follow-up
- Not only descriptive features, but credible answers to practical questions
- Independency from fund sources

Characteristics of the new program

- **Part of the ESC's duty and mission to provide a better understanding of medical practice in Europe**
- **Robust methodology (including health economic data)**
- **Representative of Europe**
- **Centralized at EHH (EORP Department) and conducted in collaboration with ESC Constituent Bodies (National Societies, Associations and Working Groups)**
- **In cooperation with, but Independent from, Industry (database ownership, publication policy)**

Models of Registries

- **General**

- To assess the management of diseases of major epidemiological impact on Public Health

- **Sentinel**

- To assess the impact of interventional procedures, imaging techniques, therapeutic tools

- **Specific Topics**

- to assess epidemiology and management of rare, complex, and demanding conditions

Provisional Programme

2009	2010	2011	2012
Heart Failure Pilot	Heart Failure Long-term	Heart Failure Long-term	Heart Failure Long-term
Pregnancy in Cardiac Diseases	Pregnancy in Cardiac Diseases	Pregnancy in Cardiac Diseases Long-term	Pregnancy in Cardiac Diseases Long-term
	Atrial Fib. Ablation Pilot	Atrial Fib. Ablation Medium-term	Atrial Fib. Ablation Medium-term
	Percutaneous Valve Pilot	Percutaneous Valve Pilot	Percutaneous Valve Long-term
		Angina/IHD Pilot	Angina/IHD Long-term
		Cardiomyopathies Long-term	Cardiomyopathies Long-term
			Atrial Fibrillation Pilot
			EUROASPIRE IV (if fully supported)

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FASTTRACK
ESC Congress

EURObservational Research Programme: The Heart Failure Pilot Survey (ESC-HF Pilot)

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<http://eurjhf.oxfordjournals.org/cgi/content/full/hfq154>



Representativeness of countries/ centers and consecutiveness of patients

● Countries

■ 12 European countries

- 4 Western European (Austria, France, Germany, the Netherlands)
- 2 Eastern European (Romania, Poland)
- 3 Southern (Greece, Italy, Spain)
- 3 Northern European (Denmark, Norway, Sweden)

Representativeness of countries/ centers and consecutiveness of patients

● Centers

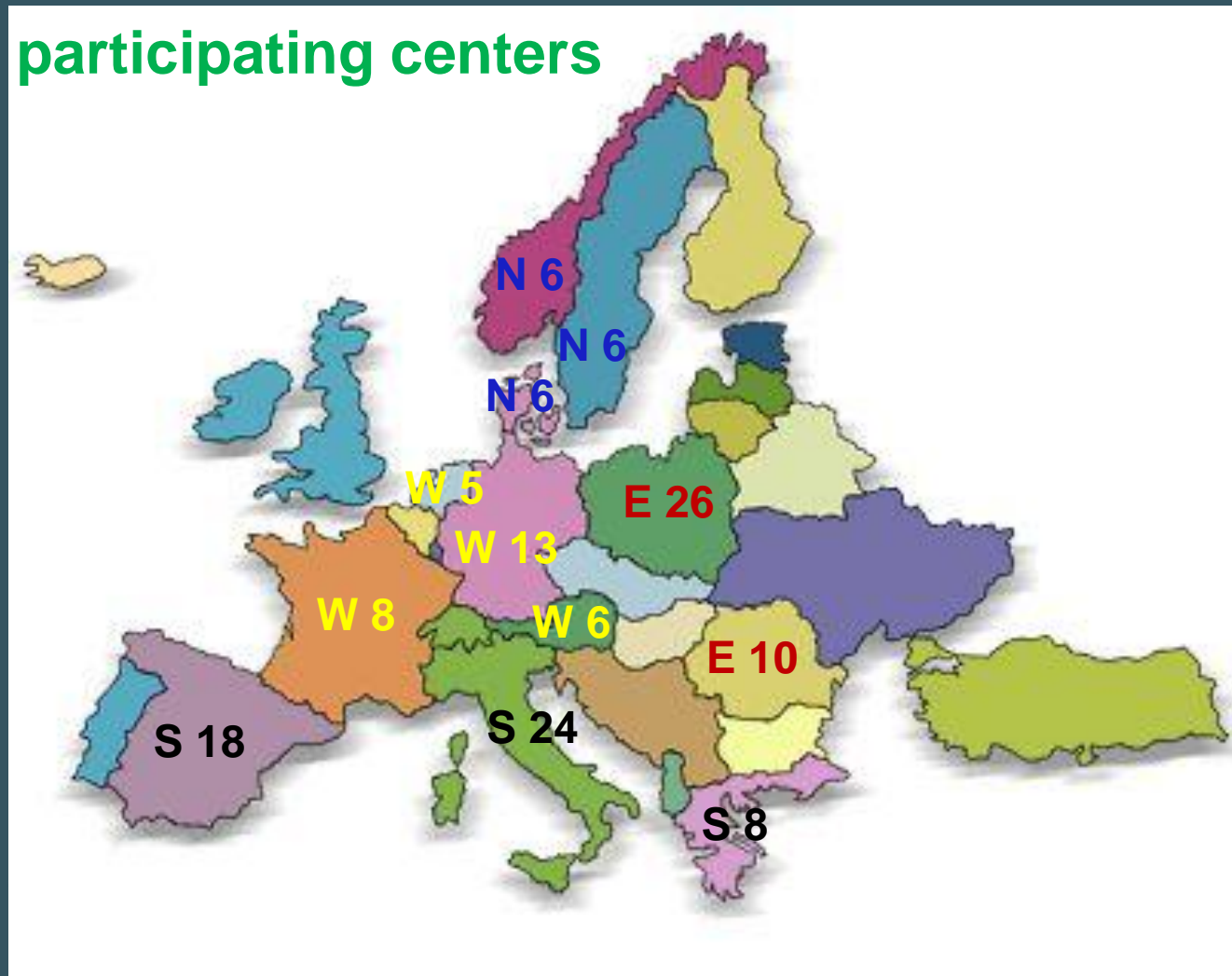
- Defined number of centres
 - one center/2 million people
- Ratio for center representativeness:
 - 1 with cardiac surgery
 - 2 with interventional cardiology (PCI/CRT/ICD)
 - 3 community centres with no surgery or interventional cardiology

Representativeness of countries/ centers and consecutiveness of patients

● Patients

- Both acute and chronic HF
- Each centre will have to include consecutive patients admitted or visited in 1 day per week of 8 consecutive months

HF Pilot 136 participating centers



Regions:

Northern (N) = 18 centers
Eastern (E) = 36 centers
Western (W) = 32 centers
Southern (S) = 50 centers

Enrolment period:

October 2009 - May 2010

HF Pilot

5118

patients enrolled in 136 centers



1892 (37%)

In-hospital patients
(AHF)



3226 (63%)

Out-patients with
chronic heart failure
(CHF)

1-year follow-up still ongoing

HF-Pilot: Next steps

- Collection of follow-up data till the end of May 2011
- Data base locked by the end of June 2011
- Statistical analysis in July-August
- Final results in Paris at the ESC Congress 2011

**From the Pilot to the
Long-Term Registry
(*data collection started
on April 14, 2011*)**

HF Long-Term Registry

- **To describe** the demographic, clinical, and biological characteristics, and the use of resources in outpatients and inpatients with HF, followed by a representative setting of ESC cardiology centers
- **Specific attention** will be focused on:
 - preserved EF
 - relevant co-morbidities, such as COPD and diabetes mellitus
 - better definition of clinical profiles of patients with acute HF
 - cardiogenic shock
 - prognostic models
 - reasons for non utilization or under-dosage of EB treatments with respect to the recommendations of guidelines

Prescribed pharmacological treatments for CHF (*n.* 3226 pts)

	Total
ACE-i, %	64.9
ARBs, %	27.0
ACE-i/ARBs, %	88.5
Betablockers, %	86.7
Digitalis, %	20.6
Diuretics, %	82.8
Aldosterone blockers, %	43.7
Nitrates, %	15.6
Antiplatelets, %	47.9
Oral anticoagulants, %	42.6

Prescribed RAAS blockers and their dosages

	Rate of use %	Dosage mg/die Median [IQR]	Target dose %
Ramipril	50.1	5 [3.75-10]	38.2 ^a
Enalapril	27.8	10 [10-20]	46.2 ^b
Other ACE-i	22.1		

^a target dose 10 mg/die, ^b target dose 20 mg/die

	Rate of use %	Dosage mg/die Median [IQR]	Target dose %
Candesartan	34.7	16 [8-32]	28.0 ^a
Losartan	26.4	50 [25-50]	19.7 ^b
Valsartan	25.7	160 [80-160]	16.7 ^c
Other ARBs	13.2		

^a target dose 32 mg/die, ^b target dose 100 mg/die, ^c target dose 320 mg/die



Heart Failure Long-Term Registry


Medications

(Demo only) Click to switch type of patient: [Hospitalised](#)

4.1 Medications and Doses

CV drugs	Prior	During hospitalisation	Discharge
		<input type="button" value="Copy from prior"/>	<input type="button" value="Copy from hospital"/>
ACE inhibitors?	Ramipril <input checked="" type="checkbox"/> Dose 5 <input checked="" type="checkbox"/> mg	Ramipril <input checked="" type="checkbox"/> If yes: 5 <input checked="" type="checkbox"/> mg	Ramipril <input checked="" type="checkbox"/> If no: <input type="text"/> <input type="button" value="↓"/> Contraindicated <input type="text"/> <input type="button" value="↓"/> Not tolerated <input type="text"/> <input type="button" value="↓"/> Reason for target dose not being reached: <input type="text"/> <input type="button" value="✎"/> Cough Worsening renal function Symptomatic hypotension Hyperkalemia Angioedema Other

Messaggio dalla pagina Web



ESC Guidelines target do for Ramipril is 10 mg!

2965

Total population of out-patients with chronic HF



1109 (37.4%)

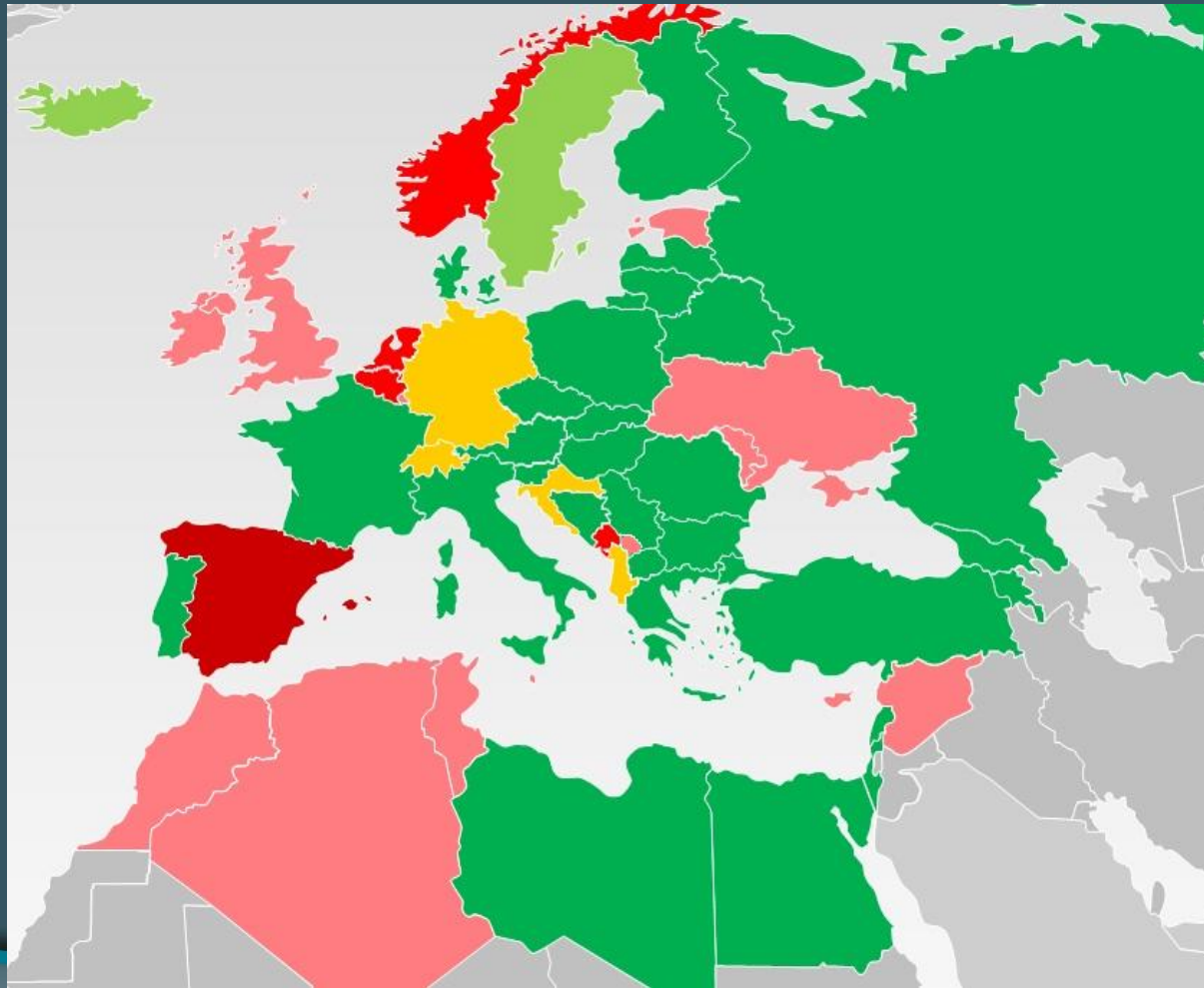
NYHA II-III, EF \leq 35%, at least 2 neurohormonal blockers
To be implanted with ICD according to guidelines



363 (32.7%)

Actually implanted

HF Long-Term Registry: participating countries Up to May 19, 2011



28 Accepted

2 Accepted to merge
National databases

4 Pending decisions

14 Not yet answered

5 Didn't accept

Persisting issues

- Consecutiveness
 - 1 day per week data collection
- Representativeness
 - Different country dimensions (revise the rule of 1 center/2 millions people)
 - Different organization in the care of HF
 - Specific country by country approach
- Quality of data and completeness of follow-up
 - Centralized computer-based quality control
 - Strong collaboration of the NCs and NSs
 - On-site (light) monitoring

The concept for an ESC Heart Failure registry: Conclusions-1

- Independent source of data that allows to
 - Assess and monitor standards of care
 - Enable comparisons on an international level
 - Optimize best practices, health care for unmet needs
 - Address unanswered clinical questions
 - Identify and prioritize unmet needs to focus future research

The concept for an ESC Heart Failure registry: Conclusions-2

- Acceptable representativeness, consecutiveness, and completeness of follow-up data
- Quality of data comparable to that of trials
- Information on the whole spectrum of the HF clinical presentations