



# Advantages and disadvantages with a registry in heart failure

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# Agenda

- Definition
- Advantages:
  - Descriptive registries in HF
  - Quality improvement registries in HF
- Disadvantages
  - Think about alternatives
  - Registry *versus* RCT
- Conclusion

# Definition

- Organized programme for the collection, storage, retrieval, and dissemination of clearly defined set of data collected on identifiable individuals for a specific and specified purpose
- Systematic data collection programme:
  - functioning in patient management or research
  - standardized, and complete dataset including associated FU
- Different types of patient registries:
  - prospectively and systematically collected for a group of patients with a common disease or therapeutic intervention

Chronic disease-specific,  
syndrome, condition

Therapeutic  
(exposure, device, surgical tt)

# Peripheral applications of registries

- Difference between the registry *per se* and the applications of a registry:
  - peripheral applications make use of registry data but are not required to create a registry
- “Good” registry should function as a clinical support system:
  - registries should provide data as feedback to physicians submitting information to the dataset

# Advantages of registries in HF

- **1/ Focus on pt management and the use of treatment guidelines**
  - **Rapidly** collect data in **large numbers** of pts
  - cross sectional views of multiple clinical and demographic aspects
    - repeated sample provides a dynamic estimate of the changing patterns of the disease
    - evaluate how therapies impact outcomes
- **2/ Improve quality of care**
  - using physician/pt reminder systems / algorithm to improve FU and care
  - information on the physician's adherence to guidelines, pts' outcomes
  - compare their own population and therapeutic strategies with that of other clinicians, or the aggregate dataset
  - => participating to a registry have an important impact on medical practice / conventional continuous medical education

# Advantages of registries in HF

- **3/ Useful for population-wide healthcare improvement** by enabling hypothesis generation or retrospective (pre–post) studies:
  - estimation of mortality, morbidity, resource utilization in every day practice
  - provide insights for clinical studies and rise questions that lead to clinical trials
  - compare disease management from countries to countries

# Rare disease registries (cardiomyopathies)

- **1<sup>st</sup> step in estimation of prevalence or incidence**
  - fundamental early step in the understanding of the natural history of disease and the development of clinical endpoints
  - identification of biomarkers and treatment
  - building a cause for future research
- **Genetic studies:**
  - identification of new disease, better phenotype characterisation
- **First born from government departments/institutional research/centres and networks for rare disease to support public health functions**
  - now patient driven organizations and industry

# Descriptive registries



# An international perspective on heart failure and left ventricular systolic dysfunction complicating myocardial infarction: the VALIANT registry

- Nested registry as part of the VALsartan In Acute myocardial iNfarction (VALIANT) trial to examine the incidence of HF and/or LVSD complicating contemporary MI,

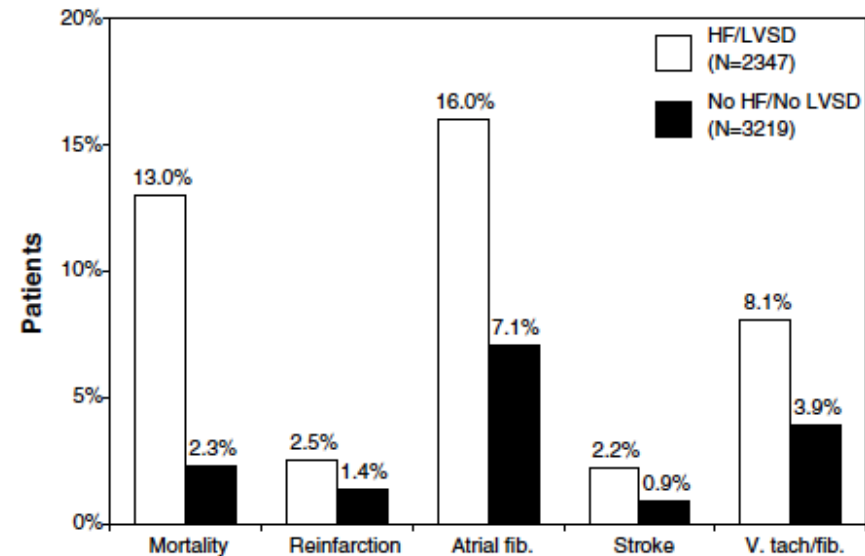
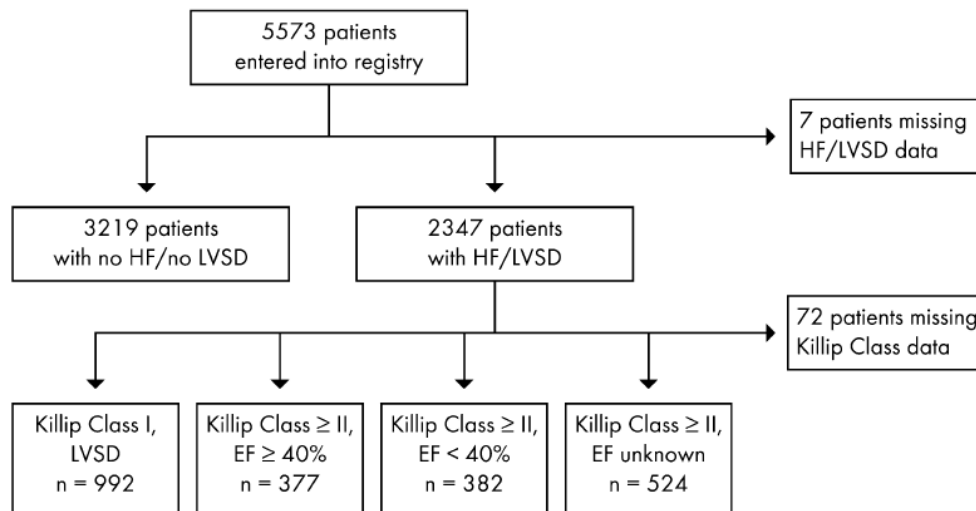


Fig. 2 In-hospital clinical events among patients with and without HF/LVSD.  $P < 0.001$  for all events except reinfarction. fib., fibrillation; V. tach/fib., ventricular tachycardia or fibrillation.

# Quality improvement registries

# Characteristics and outcomes of patients hospitalized for heart failure in the United States: Rationale, design, and preliminary observations from the first 100,000 cases in the Acute Decompensated Heart Failure National Registry (ADHERE)

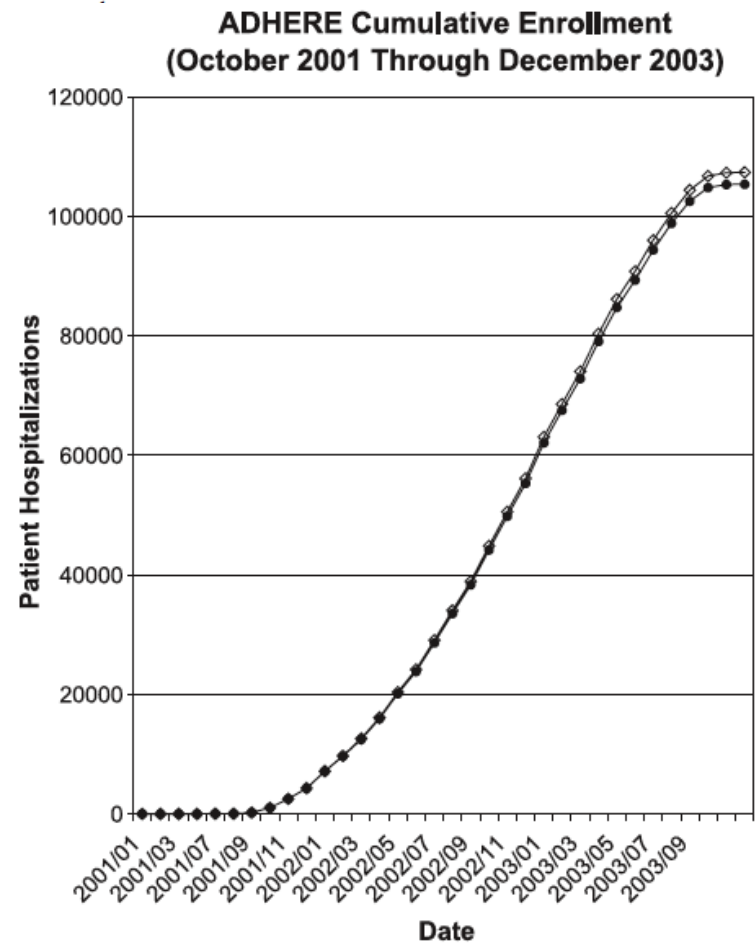


Geographic distribution of the first 263 ADHERE sites across the United States enrolling patients. These include both academic and community centers.

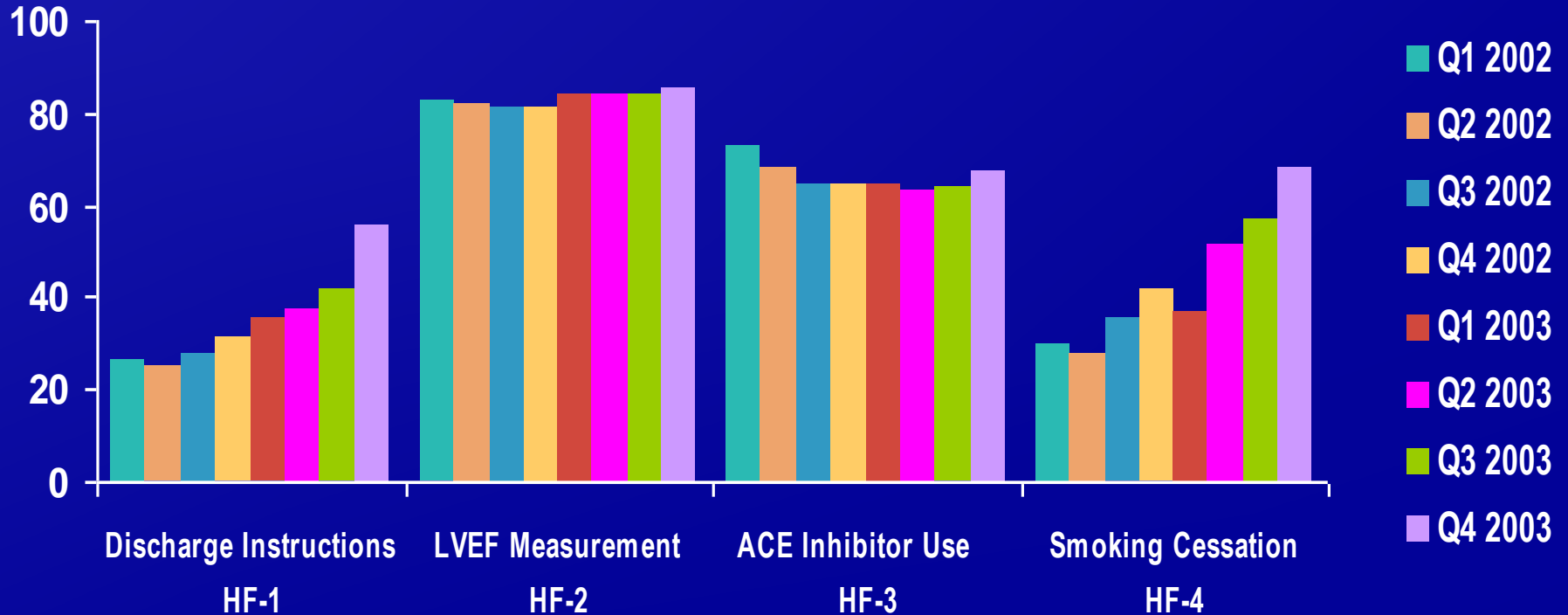
- Large, national database describing the clinical characteristics, physician practice and treatment patterns, and outcomes of pts hospitalized with acute HF.
- Specific objectives:
  - (1) **describe the demographic and clinical characteristics of pts** hospitalized with acute HF (including specific subgroups of interest)
  - (2) to characterize the **initial emergency department evaluation** and subsequent **inpatient management** of pts
  - (3) to identify pt characteristics and medical care practices associated with improved health outcomes in pts hospitalized with acute HF
  - (4) to characterize **trends over time** in the management of acute HF
  - (5) to **assist hospitals in evaluating and improving quality of care** for pts hospitalized with HF.
- FU data were not currently obtained as part of the ADHERE

# Characteristics and outcomes of patients hospitalized for heart failure in the United States: Rationale, design, and preliminary observations from the first 100,000 cases in the Acute Decompensated Heart Failure National Registry (ADHERE)

- > 50 publications
- Initial data from the registry provided new insights into the clinical characteristics of hospitalized HF pts
- Renal dysfunction is a hallmark of this pt population:
  - 30% of pts hospitalized with heart failure have a history of renal insufficiency
  - 20% of the pts have serum creatinine levels > 2.0 mg/dL



# Trends in Quality of Care at Discharge in ADHERE: Q1 2002 to Q4 2003



Q1 2002	n= 8,198	Q1 2003	n=17,735
Q2 2002	n=11,289	Q2 2003	n=16,719
Q3 2002	n=14,430	Q3 2003	n=13,984
Q4 2002	n=16,925	Q4 2003	n= 10,265

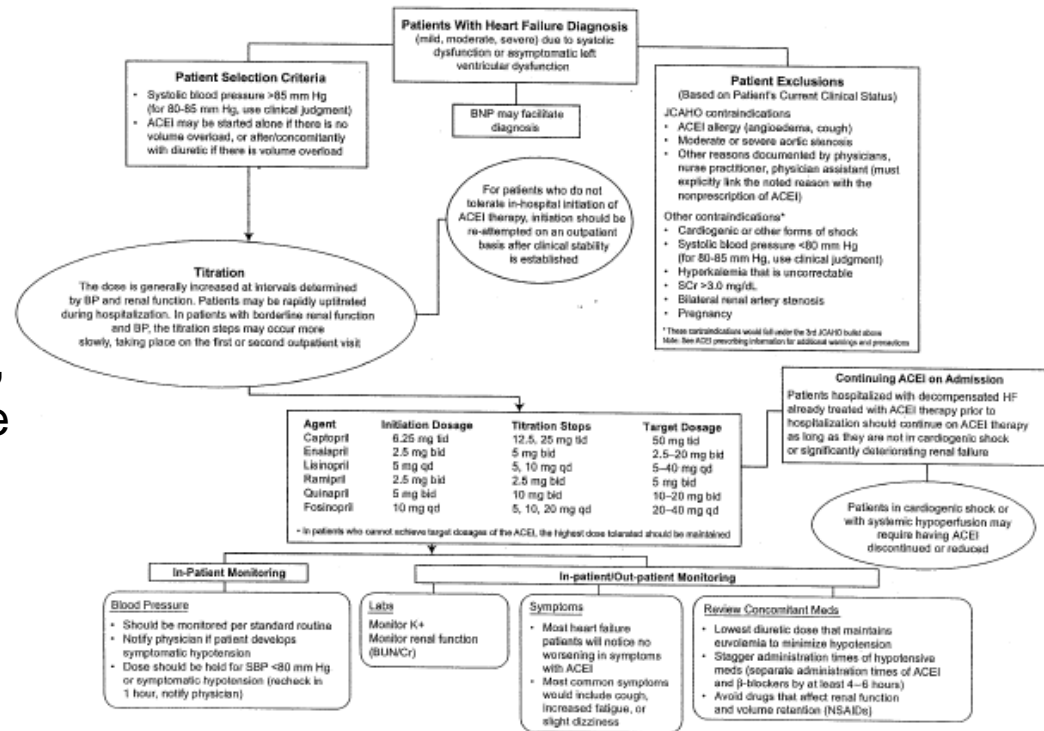
# Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF): Rationale and Design

- **Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure, OPTIMIZE-HF program:**
  - designed to improve medical care and education of hospitalized pts with HF
  - accelerate the initiation of evidence-based HF guideline recommended therapies by administering them before hospital discharge.
  - to rapidly improve the standard of HF care in the hospital and outpatient settings
- A significant proportion of eligible patients with HF are not receiving guideline-recommended treatment
  - initiation of beta-blockers is often delayed because of concern that early initiation of these agents may exacerbate HF.
- Recent studies suggest:
  - BB can be safely and effectively initiated in pts with HF before hospital discharge
  - clinical outcomes are improved, ↓ mortality and hospitalization
  - ↑ rate of BB use after hospital discharge, with no increase in hospital length of stay, no increase in the risk of worsening of HF

# Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients with Heart Failure (OPTIMIZE-HF): Rationale and Design

## OPTIMIZE-HF in-hospital ACEI/BB HF treatment algorithm

- A registry component:
  - comprehensive database of the hospitalized HF population focusing on admission to discharge and 60- to 90-day FU
  - designed to evaluate the demographic, pathophysiologic, clinical, treatment, and outcome characteristics of pts hospitalized with HF.





# Association Between Performance Measures and Clinical Outcomes for Patients Hospitalized With Heart Failure

- **OPTIMIZE-HF:** 25 related publications from 2004 to 2011
- To examine the relationship between ACC/AHA performance measures for patients hospitalized with heart failure and relevant clinical outcomes.

**Table 3.** Unadjusted Performance Measure Conformity in Patients With and Without Subsequent Mortality and Mortality/Rehospitalization

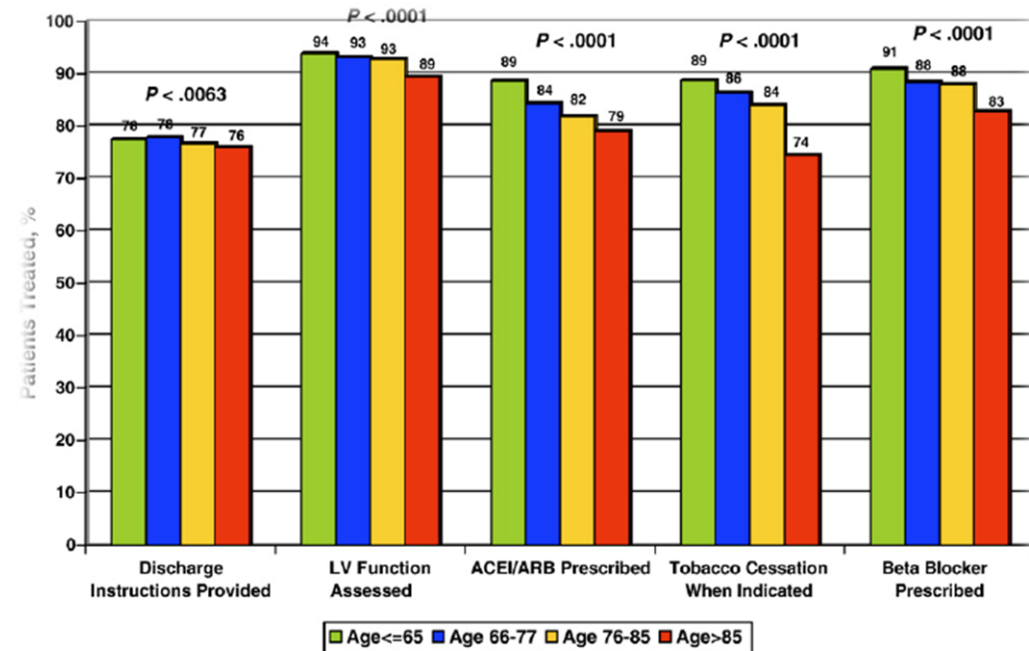
Performance Measures	No./Total (%)					
	Mortality			Mortality or Rehospitalization		
	Measure Applied (n = 481)	Measure Not Applied (n = 5125)	P Value	Measure Applied (n = 2033)	Measure Not Applied (n = 3577)	P Value
Discharge instructions	151/238 (63.4)	2478/3732 (66.4)	.35	876/1331 (65.8)	1754/2640 (66.4)	.69
Evaluation of left ventricular systolic function	305/356 (85.7)	3803/4246 (89.6)	.02	1447/1639 (88.3)	2662/2964 (89.8)	.11
ACE inhibitor/ARB for left ventricular systolic dysfunction	<u>86/118 (72.9)</u>	<u>1474/1734 (85.0)</u>	<u>&lt;.001</u>	<u>513/651 (78.8)</u>	<u>1047/1201 (87.2)</u>	<u>&lt;.001</u>
Smoking cessation counseling	34/53 (64.2)	567/785 (72.2)	.21	177/268 (66.0)	424/570 (74.4)	.01
Warfarin for atrial fibrillation	75/155 (48.4)	755/1420 (53.2)	.26	312/617 (50.6)	518/959 (54.0)	.18
β-Blocker at discharge	<u>104/141 (73.8)</u>	<u>1596/1854 (86.1)</u>	<u>&lt;.001</u>	<u>569/694 (82.0)</u>	<u>1132/1302 (86.9)</u>	<u>.003</u>

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker.



# Influence of age on the management of heart failure: Findings from Get With the Guidelines–Heart Failure (GWTG-HF)

- The OPTIMIZE HF paved the way to the GWTG-HF program
- GWTG-HF participating hospitals
  - teaching and nonteaching, rural and urban, and large and small hospitals from all census regions of the USA
- Online submission of clinical information
  - medical history, hospital care, outcomes are assessed using consistent categories and standards.
  - adults hospitalized with new or worsening HF as the primary reason for admission or with significant HF symptoms that developed during a hospitalization in which HF becomes the primary discharge diagnosis.

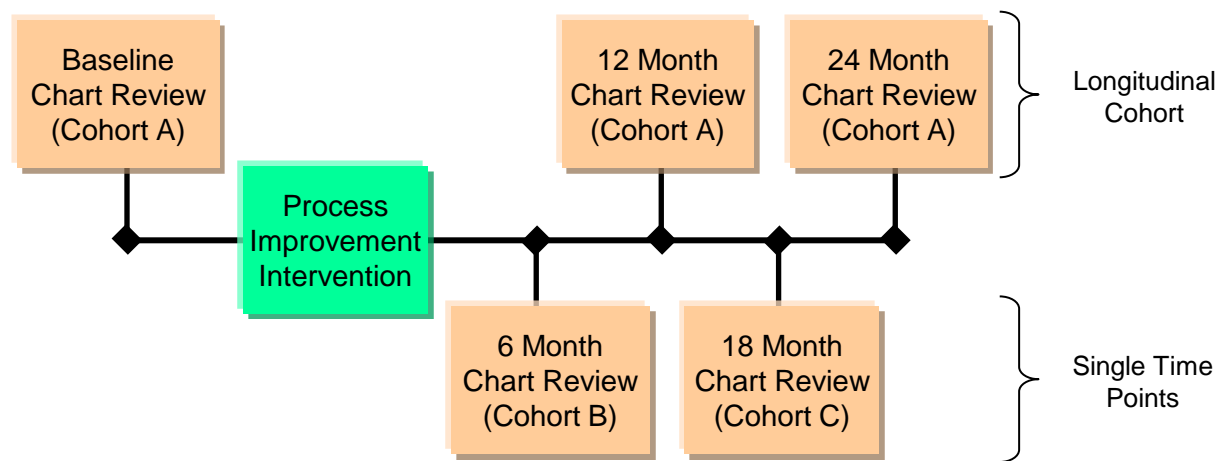


Age-related differences in GWTG-HF quality indicators.

# Improving the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting: The IMPROVE HF performance improvement registry

## Quality improvement registries in the outpatient arena

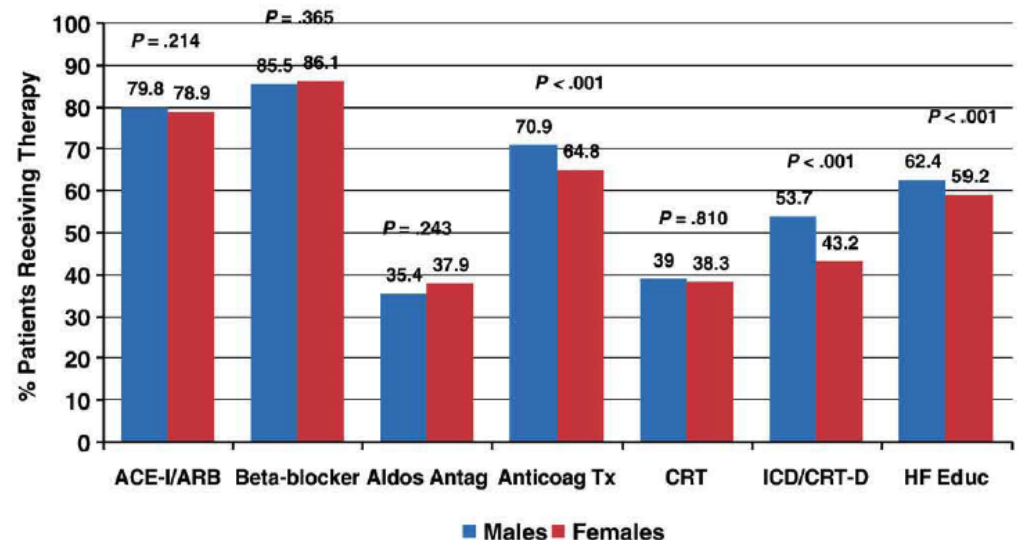
- IMPROVE HF
  - designed to characterize the current outpatient management of systolic HF
  - assess the effect of practice-specific process improvement interventions
- 7 performance measures to quantify the quality of outpatient HF care were developed
  - primary objective is to observe a **relative  $\geq 20\%$  improvement in at least 2 of the 7 performance measures at 24 months**, compared with baseline.
- > 15 publications since 2007



# Heart Failure Care in the Outpatient Cardiology Practice Setting: Findings from IMPROVE HF

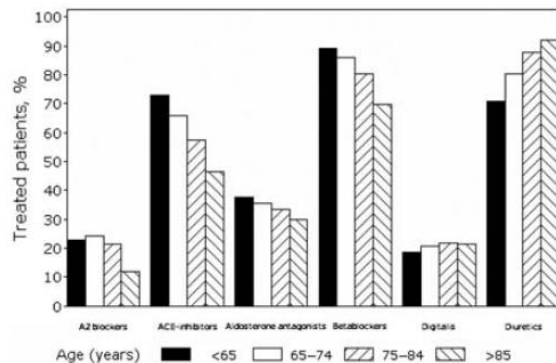
- Use of ACEI/ARB and BB among eligible patients in the outpatient cardiology practice setting is higher than previously reported
- Baseline use of evidence-based therapy in the outpatient cardiology practice setting is still below optimal, particularly for:
  - Aldosterone antagonist
  - ICD and CRT device therapy
  - HF education

- Patient age and sex are independently associated with reduced rates of some, but not all, HF therapies in outpatient cardiology practices



# Heart failure registry: a valuable tool for improving the management of patients with heart failure

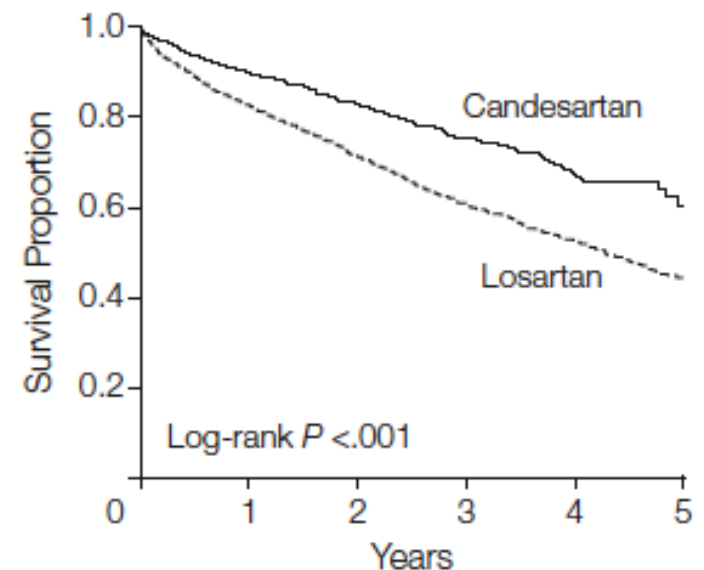
- The Swedish Heart Failure Registry (S-HFR)/RiksSvikt (2003)
  - Internet-based registry, 70 variables (demography, concomitant diseases, diagnostic procedures, haemodynamics, laboratory data, medication).
- 1 year of follow-up:
  - data on mortality and morbidity, a questionnaire sent out to all patients (medication, quality of life, functional capacity, 80% response rate).
- 2003-2007: 16 117 patients
- National quality control registry of HF pts
  - Participating units are regularly provided with online updates:
    - reports on the use of diagnostic tools, recommended medications
  - Possibility to compare centre data with national averages
    - assess its own clinical practice and make adjustments.
  - Evaluation of improvement in quality of life or functional capacity.
  - Assess treatment modifications after 1 year of FU.



# Association of Candesartan vs Losartan With All-Cause Mortality in Patients With Heart Failure

- 44 548 registrations from 30 254 unique patients from 62 hospitals and 60 outpatient clinics.
- Valsartan and other ARBs were excluded due to small numbers resulting in 5139 individuals receiving candesartan (n=2639) or losartan (n=2500) for this study.

**Figure 1.** Kaplan-Meier Estimates of Survival of Patients Receiving Candesartan and Losartan



No. at risk	0	1	2	3	4	5
Candesartan	2639	1739	957	426	125	30
Losartan	2500	1692	1097	646	359	178

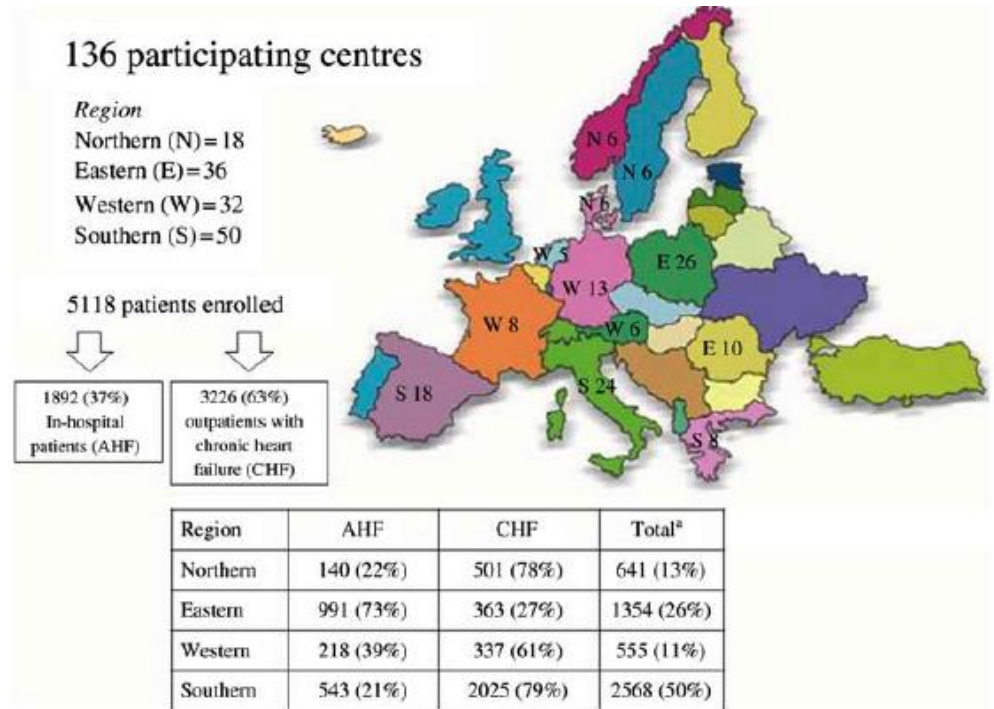
# Disadvantages : think about the alternatives

- Before considering a registry ...
  - Motivations, long-term commitment and long-term funding
    - Founding for data collections and capture in hospitals/centres
      - multi national registries that capture clinical data can employ dozens to hundreds of people at tremendous expense
  - Hysteresis:
    - data collection, documentation, quality control activities have to be conducted for many years before a registry becomes fully productive for epidemiological purpose
  - Small pilot investigations or review of previous work can help determine the suitability of the data source to meet purpose of the registry
- More efficient and cheaper alternatives to registries should be considered:
  - cross sectional surveys, short term or limited catchment studies



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

- Capture all the relevant clinical information of pts with chronic HF, including acute episodes of decompensation
- Improve our knowledge on the epidemiology and outcomes of real-world HF pts
- The primary objective
  - to describe the clinical epidemiology of outpatients and inpatients with HF
  - diagnostic/therapeutic processes applied in the 12 participating European countries.
  - validating the structure, performance, feasibility, and quality of the data set,



- Representative centers and countries
- => intention of continuing the survey into a permanent registry.

# Disadvantages : think about the alternatives

- Before considering a registry ...
  - Motivations, long-term commitment and long-term funding must be thoroughly explored
    - multi national registries that capture clinical data can employ dozens to hundreds of people at tremendous expense
  - Hysteresis:
    - data collection, documentation, quality control activities have to be conducted for many years before a registry becomes fully productive for epidemiological purpose
  - Small pilot investigations or review of previous work can help determine the suitability of the data source to meet purpose of the registry
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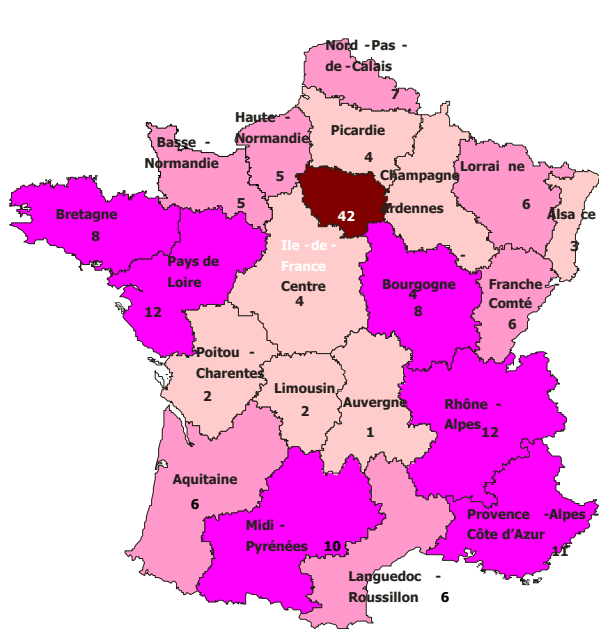


## OBJECTIVES

- Epidemiological data on acute heart failure illustrating the "real life"
  - different types of hospital/departments
  - all patients
- Medical courses (before, during, after hospitalisation), clinical scenarios
- Resource use, treatments
- Changes in treatment during follow-up, outcomes
- To create a national network on heart failure

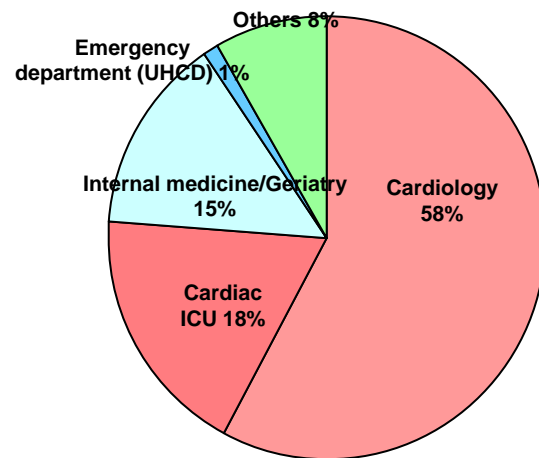
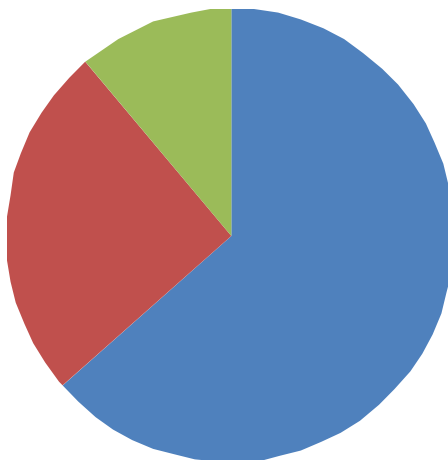
→ "snapshot" on 12 march 2009

- 170 hospitals, 1818 selected patients



DOM TOM : 2

- General Hospital
- University hospital
- Private hospitals



# Randomized clinical trials versus registries

- For any comparison of treatment effectiveness the **randomized clinical trials (RCT) remain the ideal, and the only credible, means for conclusion.**
- In registries
  - treatment may change over time, adherence is not monitored
  - clinical variables that may affect choice of medications and strategies: hypertension, diabetes, duration of HF, renal function
  - diagnostic coding by the site hospital, documentation of medical history and management during hospitalization may be incomplete or imprecise
  - data are gathered retrospectively
  - despite extensive covariate and propensity adjustment, residual confounding cannot be excluded, thus may only be demonstrating associations, rather than cause-and-effect relationships

# Randomized clinical trials versus registries

- BUT registry studies have advantages compared with RCT:
  - Registry study provides information useful for every day clinical care of a broad unselected population
  - strict inclusion/exclusion criteria in RCT limits applicability to many patient groups (elderly patients)
  - RCT may understate “real world” differences
    - strict inclusion criteria, and careful monitoring yield good prognosis and dilute any differences between therapies

# Conclusion and future of registries

- Reflect actual clinical practice and partially avoid the selection bias that characterises RCT
  - registries will only provide answers to the questions asked
  - will never replace RCT
- Serve as tools to improve medical practice
- Will be shaped by technology advances:
  - Impact of computer technology over the past 10 years on the development of registries, affecting sources, volume, quality, promotion (social network), and FU
  - (european) standards are required to enable sharing of content, re-use of data from clinical settings or patients reports
  - Involvement of patients patient controlled sharing of their electronic health records?

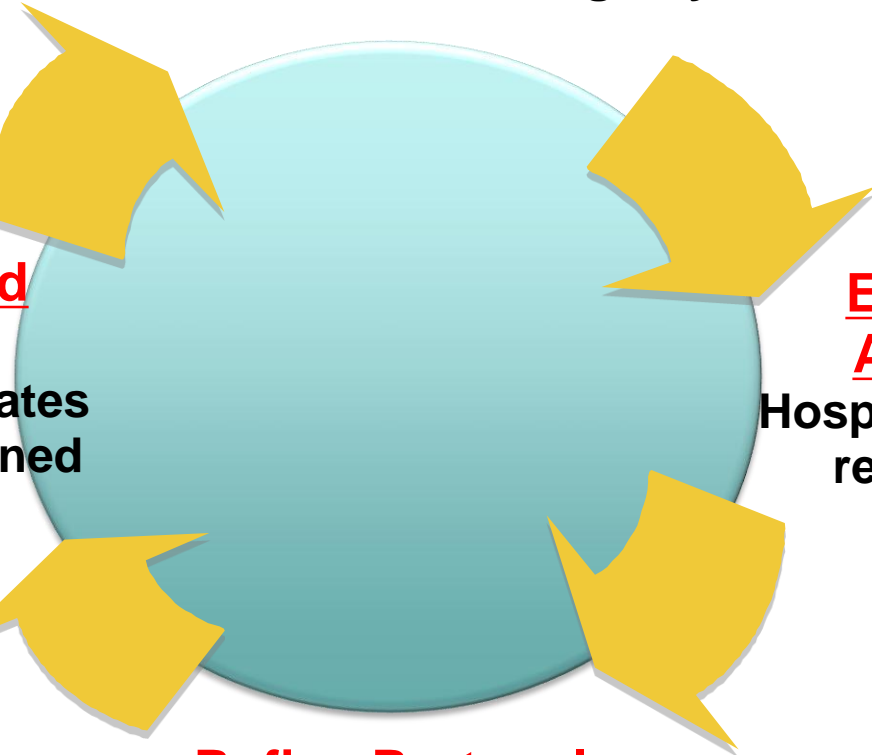
# Registry critical pathways Performance Improvement Process

**Find and support a champion**



**Assess HF Treatment Rates**

**Enter Data into the registry**



**Evaluate and  
Assessment**

**Hospital team reviews  
registry reports**

**Refine Protocol**

**Hospital team identifies  
areas for improvement and uses tool kit**

**Implement Refined  
Protocol**

**Hospital team coordinates  
implementation of refined  
protocol and tools**