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# Quality of adherence to guideline recommendations for life-saving treatment in heart failure: an international survey

**Submission date**
05/02/2015

**Recruitment status**
No longer recruiting

**Registration date**
07/05/2015

**Overall study status**
Completed

**Last Edited**
14/06/2023

**Condition category**
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Heart failure (HF) is associated with a high mortality and morbidity, reduced quality of life, and increasing health care costs in Europe as well as across the world. The prescription of evidence-based therapies recommended by guidelines is the most effective way of ensuring that patients receive high-quality and optimal care. Surveys of patients with HF often provide descriptions of the clinical characteristics and management of patients and of outcomes, but we lack data on the use of guideline-recommended therapies in all potentially eligible patients. This is the aim of this study.

Who can participate?
Adult outpatients with chronic HF and left ventricular systolic dysfunction (LVSD).

What does the study involve?
Physician selection is based on the best available sources, either local or regional, concerning the epidemiology and medical care data, including available market data and epidemiological surveys. A general target of 10-20 consecutive patients per investigator was used ensuring the best possible representative inclusion of the HF population in each practice setting.
Information collected includes: demographics; medical history; risk factors and lifestyle; results of physical examination; current symptoms; laboratory values if available; and current medical treatments. Adherence to evidence-based pharmacologic treatments recommended by guidelines will be determined by calculating the adherence score, taking into account the treatment eligibility criteria and the existence of contraindications to drugs based on the international guidelines on management of HF.

What are the possible benefits and risks of participating?
This information is expected to be important to physicians, care providers, and health services, by identifying gaps between evidence and practice and areas for improvement in the post-discharge care of outpatients with chronic HF and LVSD. Physicians have been instructed to continue management and treatment of patients according to their usual practice and the new international guidelines for the management of HF. No specific tests or therapies will be

prescribed as part of this survey, and the management of patients will be completely left to the discretion of participating physicians.

Where is the study run from?
547 centres from 36 countries

When is the study starting and how long is it expected to run for?
January 2013 to September 2018

Who is funding the study?
Servier (France)

Who is the main contact?
Professor Michel Komajda

### Study website
www.qualify-survey.com

## Contact information

### Type(s)
Scientific

### Contact name
Dr Michel Komajda

### Contact details
Groupe Hospitalier Pitie - Salpetriere
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75013

## Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

## Study information

### Scientific Title
QUAlity of adherence to guideline recommendations for LIfe-saving treatment in heart failure: an international surveY: an observational study

## Acronym
QUALIfY

## Study objectives
1. Assess clinical characteristics and management of outpatients with heart failure
2. Focus on how monitoring of disease status can be used to guide treatment
3. Evaluate the prescription of recommended therapeutic options in eligible patients
4. Assess adherence to the new European Society of Cardiology guidelines for the management of heart failure

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval obtained in every country in accordance with local regulations. All 557 centres obtained ethics approval before recruitment of the first participant (the first approval was obtained on 10/06/2013 from the Ethics Committee at the National Institute of Cardiovascular Diseases, Slovakia; approval for the last site was on 20/09/2014 from McGill University Health Centre Biomedical D, Canada).

## Study design
Prospective observational longitudinal survey

## Primary study design
Observational

## Secondary study design
Longitudinal study

## Study setting(s)
Other

## Study type(s)
Other

## Participant information sheet

## Health condition(s) or problem(s) studied
Heart failure

## Interventions
Non-interventional survey

## Intervention Type
Other

## Primary outcome measure
1 To evaluate physician’s adherence to HF guidelines by measuring prescriptions modalities of recommended HF medications
2. To calculate an adherence score

3. To analyze the reasons for non-adherence
4. To assess the impact of adherence level on clinical outcomes

Measured at baseline and at 6, 12 and 18 months.

### Secondary outcome measures
To characterize the clinical characteristics and management of outpatients with HF and left ventricular systolic dysfunction (LVSD).

Measured at baseline and at 6, 12 and 18 months.

### Overall study start date
01/01/2013

### Completion date
01/09/2018

## Eligibility

### Key inclusion criteria
Outpatients with chronic heart failure:
1. > 18 years of age
2. Hospitalised for worsening of heart failure within 1–15 months
3. With LVSD as demonstrated by left ventricular ejection fraction ≤ 40% measured using the most recent echocardiogram (≤ 2 years)
4. Validation of rhythm at inclusion

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
7092

### Key exclusion criteria
1. Patients on waiting list for heart transplantation or planned implantation of left ventricular assist device; planned cardiac resynchronisation therapy and implantable cardioverter defibrillators are permitted
2. Patients with planned revascularisation
3. Patients hospitalised for cardiovascular disease within the past 4 weeks
4. Conditions hampering participation or the 18-month follow-up

### Date of first enrolment
01/09/2013

### Date of final enrolment
30/12/2014

## Locations

### Countries of recruitment
Armenia

Australia

Austria

Azerbaijan

Bahrain

Belarus

Brunei Darussalam

Canada

China

Denmark

Egypt

Georgia

Germany

Greece

Hungary

Ireland

Jordan

Kazakhstan

Korea, South

Kuwait

Lebanon

Lithuania

Malaysia

Morocco

Oman

Poland

Portugal

Qatar

Romania

Russian Federation

Slovakia

Spain

Thailand

Türkiye

Ukraine

United Arab Emirates

**Study participating centre**
**547 from 36 countries**
France
-

# Sponsor information

**Organisation**
Servier

**Sponsor details**
35 rue de Verdun
Suresnes
France
92284

**Sponsor type**

Industry

**Website**
www.qualify-survey.com

**ROR**
https://ror.org/034e7c066

# Funder(s)

**Funder type**
Industry

**Funder Name**
Servier (France)

# Results and Publications

**Publication and dissemination plan**
Planned publication in a peer reviewed journal.

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**Intention to publish date**
31/12/2016

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**IPD sharing plan summary**
Other

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/05/2016 | | Yes | No |
| Results article | | 10/02/2021 | 14/06/2023 | Yes | No |
| Results article | | 30/04/2017 | 14/06/2023 | Yes | No |