











Data standards for heart failure: the European Unified Registries for Heart Care Evaluation and Randomized Trials (EuroHeart)

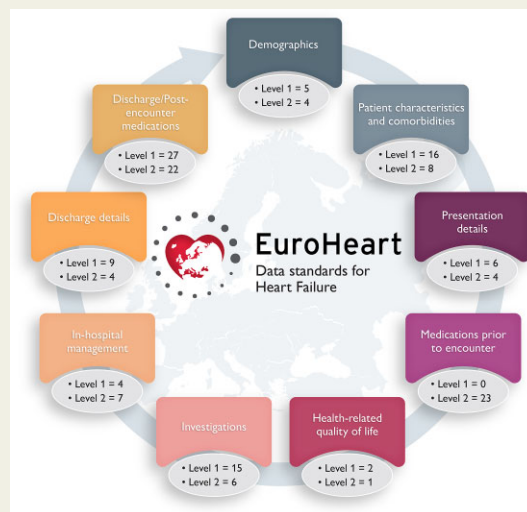
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Graphical Abstract EuroHeart: European Unified Registries for Heart Care Evaluation and Randomized Trials.

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Abstract

Standardized data definitions are essential for assessing the quality of care and patient outcomes in observational studies and randomized controlled trials. The European Unified Registries for Heart Care Evaluation and Randomized Trials (EuroHeart) project of the European Society of Cardiology (ESC) aims to create contemporary pan-European data standards for cardiovascular diseases, including heart failure (HF). We followed the EuroHeart methodology for cardiovascular data standard development. A Working Group including experts in HF registries, representatives from the Heart Failure Association of the ESC, and the EuroHeart was formed. Using Embase and Medline (2016–21), we conducted a systematic review of the literature on data standards, registries, and trials to identify variables pertinent to HF. A modified Delphi method was used to reach a consensus on the final set of variables. For each variable, the Working Group developed data definitions and agreed on whether it was mandatory (Level 1) or additional (Level 2). In total, 84 Level 1 and 79 Level 2 variables were selected for nine domains of HF care. These variables were reviewed by an international Reference Group with the Level 1 variables providing the dataset for registration of patients with HF on the EuroHeart IT platform. By means of a structured process and interaction with international stakeholders, harmonized data standards for HF have been developed. In the context of the EuroHeart, this will facilitate quality improvement, international observational research, registry-based randomized trials, and post-marketing surveillance of devices and pharmacotherapies across Europe.

Keywords

Data standards • Variables • Data definitions • Heart failure • Quality of care • EuroHeart

Introduction

Standardized data definitions are essential for the reliable monitoring and comparison of quality of care and outcomes in observational studies and form the basis for data management in randomized controlled trials. There is a lack of an international consensus about the use and description of heart failure (HF) variables including those pertinent to patient characteristics, care delivery, and outcomes.¹ As such, heterogeneity exists in the selection and definitions of data which impedes benchmarking and leads to inconsistencies that impair the interpretation of clinical studies and the acceptance of their findings.^{1,2}

The 2021 American College of Cardiology/American Heart Association Key Data Elements and Definitions for HF provides a comprehensive list of data variables relevant to the HF care process.³ It comprises around 295 data variables, but with no hierarchical specification as to which are of a greater importance—potentially limiting their uptake in clinical practice.³ Also, the dataset was developed in accordance with the North American Clinical Practice Guidelines and healthcare system characteristics and, unlike the European Society of Cardiology (ESC) recommendations, uses a locally proposed staging system for HF that has not been adopted widely outside North America. For Europe, the Cardiology Audit and Registration Data Standards project in 2004 defined a set of variables for acute coronary syndrome, percutaneous coronary intervention, and clinical electrophysiology, but not HF.⁴ The European Unified Registries for Heart Care Evaluation and Randomized Trials (EuroHeart) project is a new initiative to develop contemporary data standards for a range of cardiovascular diseases and interventions, and has to date developed international data standards for acute coronary syndrome, percutaneous coronary intervention, and atrial fibrillation, with plans for the same for transcatheter aortic valve implantation and cardiovascular outcomes among other cardiovascular areas.^{5,6} This document specifically presents the EuroHeart data standards for HF, which have been developed in collaboration with the Heart Failure Association (HFA) of the ESC.

Methods

A Data Science Group under the auspice of the EuroHeart project was established in August 2019. This comprised a project chair (C.P.G.), two medical experts (S.A. and G.B.), and a project manager.

Working and reference groups

A Working Group for the development of the 2021 EuroHeart data standards for HF was invited from members of the EuroHeart Data Science Group, HFA representatives, and selected HF experts who have experience in national or international HF registries. Names and affiliations of the Working Group members are provided in *Table A1*.

In addition, a Reference Group comprising 44 international HF experts from 34 countries was convened to review and provide feedback on the final set of variables, permissible values, and definitions.

EuroHeart methodology

We followed the EuroHeart methodology for cardiovascular data standard development.⁷ In brief, this methodology involves: (i) identification of a cardiovascular domain for development of data standards; (ii) conduction of a systematic review of the literature to synthesize a list of 'candidate' variables; (iii) selection and prioritization of variables by domain experts using a modified Delphi method; (iv) Reference Group feedback; and (v) programming the final data variables into the EuroHeart IT platform.⁷

Scope

From the outset, the Data Science Group consulted with the Working Group to decide upon the extent of the EuroHeart-HF registry. It was agreed that the registry should capture information relating to both in-patient and out-patient care because, unlike acute coronary syndrome for instance, HF is a chronic disease spanning multiple clinical settings, where treatment is often optimized and adjusted in response to disease progression, the development of comorbid disease, and the side-effects of therapy.

Systematic literature review

The EuroHeart Data Science Group conducted a systematic review of the literature on data definitions in HF (Appendix Table A2). The search included studies that defined variables relevant to HF published between 1 January 2016 and 10 January 2021. These dates were chosen to capture contemporary HF management and data variables. We included peer-reviewed randomized trials or prospective observational studies that provided definitions for at least one variable relevant to HF diagnosis, management, or outcomes. We also reviewed the data dictionaries of existing HF registries, as well as HF quality indicators and guidelines.^{8–10} Following the literature search, a ‘long-list’ of candidate HF variables was identified for potential inclusion in the EuroHeart-HF dataset.

Variable level

In the EuroHeart, variables are classified as Level 1 variables if they are used as quality indicators of HF care or are important for risk stratification, case-mix adjustment, or outcome evaluation. The EuroHeart provides clinical definitions for the Level 1 variables and implements them on the EuroHeart IT platform to facilitate their collection. Level 2 variables are further measures which may prove useful in selected areas or circumstances, but which are not universally available or useful. They complement quality assessment and may have a role in observational or randomized research. Level 2 variables are defined in the EuroHeart data standard documents, but are not implemented on the EuroHeart IT platform. Given that the end users of the EuroHeart will be healthcare providers, the EuroHeart platform allows for the addition of a third set of variables (Level 3) that can be centre- or country-specific, and may be needed for a national or local study or a quality improvement project.⁷ Level 3 variables are not defined or programmed by the EuroHeart.

Selection of the final set of variables

Using a modified Delphi method, the Working Group reviewed the list of candidate variables from the systematic review to select the final set, to decide whether they were Level 1 or Level 2, and to create permissible values and definitions. The EuroHeart criteria for data standard development (importance, evidence base, validity, reliability, feasibility, and applicability) were used to guide the selection process.⁷ In total, six virtual meetings were conducted between January 2021 and April 2021, with a large volume of e-mail correspondence between the meetings.

Implementation

After arriving at the final set of variables, the Data Science Group worked with the Registry Technology group of the EuroHeart project to programme the Level 1 variables into the EuroHeart IT platform. For each variable, details were provided to the IT team regarding the clinical setting(s) in which the variable is applicable, the permissible ranges for the numerical response options, and the inter-relationships between the chosen variables to facilitate the design of a logical prototype for data entry. In addition, the Registry Technology group integrated the specifications that are needed for the calculation of the ESC quality indicators for HF on the EuroHeart IT platform.⁹

Results

The systematic review retrieved 1715 articles. Of these, 372 met the inclusion criteria and were used to extract candidate variables (Appendix Figure A1). Of the 189 candidate variables considered for inclusion, 107 (57%) were obtained from the systematic review

and 82 (43%) from the Clinical Practice Guidelines and quality indicators. Following the modified Delphi method, 84 Level 1 variables (see Supplementary material online, Table S1) and 79 Level 2 variables (see Supplementary material online, Table S2) were selected across nine domains of HF care (Graphical Abstract).

These key domains of HF care in the EuroHeart-HF registry are the following: (i) demographics, (ii) patient characteristics and comorbidities, (iii) presentation details, (iv) medications prior to encounter, (v) health-related quality of life, (vi) investigations, (vii) in-hospital management, (viii) discharge details, and (ix) discharge/post-encounter medications. With the exception of the ‘In-hospital management’ domain, all other domains comprise variables for both the in-patient and out-patient settings as shown in Supplementary material online, Tables S1 and S2.

Domain 1: demographics

This domain was aligned with the EuroHeart acute coronary syndrome and percutaneous coronary intervention registries⁵ to minimize the burden of data collection when patients are enrolled in more than one EuroHeart registry (Figure 1). Some of the Level 1 variables within this domain capture patient-identifiable information to allow multi-source data linkage (see Supplementary material online, Table S1).¹¹ Patient-identifiable data are stored and managed locally as required by each country’s data-sharing regulations. Anonymized data that are aggregated at the centre or the country level may be shared centrally with the EuroHeart Data Centre following an agreement from both parties.

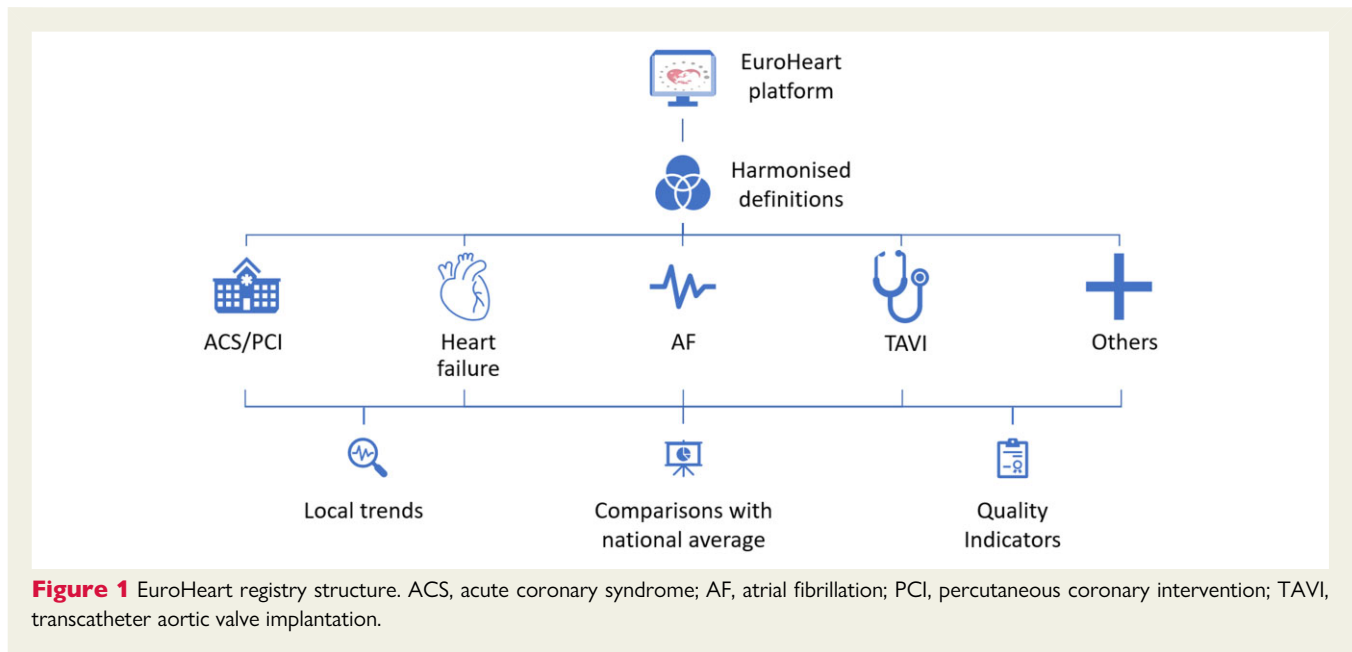
Domain 2: patient characteristics and comorbidities

This domain contains data about the patient’s characteristics at the time of registration (e.g. weight), lifestyle habits (e.g. smoking), and medical history at the time of encounter with a healthcare professional (see Supplementary material online, Table S1). In addition, this domain captures information about comorbidities that may influence the decisions for patient care, improve the prediction of outcomes,¹² or allow risk adjustments when variations in performance are evaluated (Figure 2).¹³ A wider list of characteristics (e.g. frailty) and comorbidities have also been selected as Level 2 variables and are presented in Supplementary material online, Table S2.

Domain 3: presentation details

Many patients are likely to have received a diagnosis of HF many months or years prior to initial registration. Clinically stable patients may be enrolled in clinics. Patients with worsening chronic HF or new-onset HF may be enrolled in a variety of settings. This domain may be completed serially for each patient encounter if resources to do so exist.

The presentation details domain includes the type of the clinical encounter (in-patient/out-patient), as well as the patient’s clinical status at the time of assessment (initial or recurrent). Such information may be easily captured and is of a prognostic value for risk stratification and for determining the best treatment strategy (Appendix Figure A2).¹⁴ Examples of the variables in this domain include the New York Heart Association (NYHA) class prior to encounter, as well as heart rate, systolic blood pressure, and Killip class at the



time of initial assessment (see [Supplementary material online, Table S1](#)).^{12,15}

Domain 4: medications prior to encounter

While a patient's pharmacotherapy prior to registration may provide an insight about the changes in treatment which have taken place during the episode of care, the Working Group raised concerns about the feasibility of collecting such information. Therefore, pre-registration medications were included as Level 2 variables (see [Supplementary material online, Table S2](#)), unlike medications at discharge (Domain 9).

Domain 5: health-related quality of life

Patient-reported outcome measures, particularly the health-related quality of life (HRQoL) are of importance to patients with HF.¹⁶ A number of validated HF-specific measurement tools exist for the measurement of HRQoL.¹⁷ The Kansas City Cardiomyopathy Questionnaire and the Minnesota Living with Heart Failure Questionnaire are commonly used HF-specific tools to measure the HRQoL.¹⁸ Other generic tool, such as the EuroQol-5 dimensions and the short-form survey have also been used to evaluate the HRQoL in patients with HF.¹⁹ For the EuroHeart-HF registry, information about whether the HRQoL was assessed at each encounter and which tool was used is captured as Level 1 category variables (see [Supplementary material online, Table S1](#)), with the results of the measurement as Level 2 variables (see [Supplementary material online, Table S2](#)). Notably, the EuroHeart IT platform allows the implementation of HRQoL questionnaires as Level 3 variables for those who have the desire, resources, and appropriate licensing permissions.

Domain 6: investigations

Tests such as the measurement of the left ventricular ejection fraction and plasma concentration of natriuretic peptides are important for the diagnosis of HF, assessing the effect of interventions, and

evaluating prognosis.²⁰ Other results including renal function, serum electrolytes,^{21,22} and electrocardiogram characteristics influence decisions about treatment⁸ and have a role in risk stratification ([Figure 3](#)).^{23,24} As such, these variables are included as Level 1 variables (see [Supplementary material online, Table S1](#)), with other investigations (e.g. C-reactive protein) placed as Level 2 variables (see [Supplementary material online, Table S2](#)).

Domain 7: in-hospital management

This relates to the processes of care that are delivered during episodes of hospitalization with HF ([Appendix Figure A3](#)). That is, the prescription of loop diuretics, the implantation of cardiac therapeutic or monitoring devices, heart transplantation, and the performance of interventions such as percutaneous coronary intervention and transcatheter aortic valve implantation (see [Supplementary material online, Table S1](#)). Here, there are also a number of Level 2 variables capturing information about the use of circulatory support (mechanical and pharmacological), respiratory support, and renal replacement therapy during the hospital stay (see [Supplementary material online, Table S2](#)).²⁵

Domain 8: discharge details

The 'Discharge details' domain includes information about the length of hospital stay, in-hospital deaths, and discharge information, such as weight and plasma concentration of natriuretic peptides at the time of discharge (see [Supplementary material online, Table S1](#)). Such data are important for the evaluation of outcomes of care, but also may have a role in risk stratification.²⁶ Moreover, an accumulating body of evidence supports the involvement of a multidisciplinary team (e.g. cardiac rehabilitation, HF clinics) in the management of HF and, after hospital discharge, early follow-up with a healthcare professional.^{8,27} Recently, these aspects of care have been proposed as ESC quality indicators for HF⁹ and are thus included as Level 1 variables (see [Supplementary material online, Table S1](#)). Less well-established assessments (e.g. NYHA class at discharge) or highly specialized

Smoking status ¹

Never smoked Former smoker Current smoker Unknown

Hypertension ¹

No Yes Unknown

Diabetes mellitus ¹

No Yes, diabetes mellitus type 1 Yes, diabetes mellitus type 2 Yes, diabetes mellitus of other/unspecified type Unknown

Chronic obstructive pulmonary disease ¹

No Yes Unknown

Moderate-severe chronic kidney disease ¹

No Yes Unknown

Prior stroke ¹

No

Yes, ischaemic

Yes, haemorrhagic

Yes, unspecified

Unknown

Prior myocardial infarction ¹

No Yes Unknown

Prior heart transplant ¹

No Yes Unknown

Atrial fibrillation or atrial flutter ¹

No Yes Unknown

Figure 2 Sample of the variables in patient characteristics and comorbidities domain.

interventions (e.g. referral to heart transplantation) are classified as Level 2 variables (see [Supplementary material online, Table S2](#)).

Domain 9: discharge/post-encounter medications

This domain forms the basis for the evaluation of performance and the assessment of adherence to the 2021 ESC Clinical Practice Guidelines and 2021 ESC quality indicators for HF.^{8,9} As such, for medications known to improve outcomes in patients with HF of any clinical type, data are collected not only about the class of the drug prescribed, but also about the generic name and the dose, recognizing that titration of medication may be incomplete at the time of discharge (from clinic or hospital) (see [Supplementary material online, Table S1](#)).^{8,9} These variables may also be of an importance for evaluating the changes in care and outcomes over time.²⁹

While capturing information about existing contraindications to the guideline-recommended therapy for HF may provide a more meaningful assessment of care quality,²⁹ it does increase the burden of data collection and can be difficult to obtain from routine medical records. Hence, variables that address the reason for not using guideline-recommended treatments for HF when apparently indicated are Level 2 (see [Supplementary material online, Table S2](#)).

Implementation

The Level 1 variables (see [Supplementary material online, Table S1](#)) were implemented on the EuroHeart IT platform with an interactive

demonstration of the EuroHeart platform, which includes the HF registry, may be accessed at <https://www.escardio.org/euroheart>.

Discussion

Adoption of harmonized data collection is central to improving cardiovascular care.²⁴ The lack of internationally recognized standardized data definitions has led to variability and inefficiencies in the monitoring of HF epidemiology and standards of care within and between countries.^{2,30} The EuroHeart project of the ESC, by means of a structured methodology and in collaboration with the HFA, has defined 84 Level 1 and 79 Level 2 variables for HF, which will be implemented on a bespoke IT platform to facilitate harmonized country-level quality improvement, international observational and registry-based randomized trials, and post-marketing surveillance of devices and pharmacotherapies.

The prevalence of HF and the healthcare resources required to manage it is increasing worldwide,³¹ including Europe.^{32–34} The emergence of novel therapies for HF in recent years⁸ and the emphasis on integrating these therapies with established care³⁵ has shaped the need to develop systems that ensure a continuous supply of data to monitor and improve quality of care. Clinical registries for HF highlight gaps in care delivery and geographical variation in practice.^{13,28,36,37} However, the lack of harmonized data standards for HF limits the scalability of such registries, makes international comparisons less reliable, and hinders the development of registry-based

ECG, atrial rhythm ⓘ

Sinus rhythm Atrial fibrillation or atrial flutter Paced rhythm Other Unknown

ECG, ventricular conduction ⓘ

▼

ECG, QRS duration (ms) ⓘ

Unknown

Left ventricular ejection fraction (%) ⓘ

Unknown

Left ventricular ejection fraction, range ⓘ

LVEF ≥50% LVEF 41-49% LVEF 30-40% LVEF <30% Unknown

LVEF 30-40% ⓘ

LVEF >35% LVEF ≤35% Unknown

Diastolic dysfunction ⓘ

▼

Figure 3 Sample of the variables in the investigations domain. LVEF, left ventricular ejection fraction.

randomized trials that could improve the efficiency and cost-effectiveness of both research and healthcare.^{38–40}

The EuroHeart registry provides a unique opportunity to develop and maintain an infrastructure for the utilization of structured data through which generalizable evidence can be derived to inform the management and reduce the burden of cardiovascular disease.⁶ As opposed to a cross-sectional assessment, the EuroHeart model allows the collection and analysis of longitudinal observations of the characteristics of HF and the patterns of HF care and outcomes over time.

The EuroHeart data standards for HF have been developed in collaboration with the HFA and with involvement of experts in European HF registries and a panel of HF experts from 34 countries who have provided their feedback, taking the resources available in their own countries into consideration. Furthermore, these standards have been formally endorsed by the National Cardiac Societies from 13 ESC member countries, the ESC Patient Forum, and the ESC Committee for Young Cardiovascular Professional, highlighting the level of acceptance (and need) for the EuroHeart data standards for HF among the cardiovascular community.

The developed data standards for HF extends the existing literature by providing the European perspective to other HF quality registries, such as the Get With the Guidelines (GWTG) in the United States.⁴¹ Although the EuroHeart-HF and GWTG have similar mandatory variables, some differences exist. The EuroHeart-HF records information about whether patient-reported outcome measures (e.g. health-related quality of life) were collected, and about the tool(s) used to capture these measures as Level 1 variables. However, the GWTG does not collect mandatory data about health-related quality of life. On the contrary, the GWTG mandates the collection of variables capturing the rationale for not prescribing

guideline-recommended therapies for HF (e.g. beta-blockers), while these are Levels 2 variables in the EuroHeart-HF.

The EuroHeart variables have been implemented on the EuroHeart IT platform to facilitate their integration with routine care. However, providing the computational phenotyping and coding details for these variables is beyond the scope of this project.⁴² The Working Group acknowledges that standardized data ontologies are needed to achieve semantic interoperability between registries, clinical trials and routinely collected electronic healthcare records (EHRs).⁴³ While individual centres (or countries) may integrate the EuroHeart structured variables within their EHRs to allow the seamless exchange of data between both systems, this integration needs to be performed on the local level because of the substantial variation in the EHR software amongst centres. Furthermore, we recognize the limitations of the EuroHeart methodology for data standard development. Despite the conduct of a systematic review of the literature, we relied on expert opinion for the selection of the final set of variables and this selection may be biased. Nonetheless, we believe that a working collaboration with experts who have experience in national and international registries and quality improvement projects, and the wide representation of the Reference Group has enabled a degree of robustness to the selection process. Future Working Groups may benefit from the inclusion of patients and wider members of the multidisciplinary team for HF such as nurses, pharmacists, and primary care physicians.

Conclusions

This document presents the first EuroHeart international data standards for HF which have been developed in collaboration with the

HFA using a standardized methodology. The 84 Level 1 variables have been implemented on the EuroHeart IT platform and can be adopted by HF registries around the world to harmonize the method by which HF data are captured.

Supplementary material

Supplementary material is available at *European Heart Journal* online.

Acknowledgements

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(Czechia), Alice May Moore (Malta), Erkin Mirrakhimov (Kyrgyzstan), Jan Nilsson (Sweden), Olav Wendelboe Nielsen (Denmark), Markku Pentikäinen (Finland), Anne-Catherine Pouleur (Belgium), Pawel Rubis (Poland), Inge Schjødt (Denmark), Róbert Sepp (Hungary), Hamayak Sisakian (Armenia), Hadi Skouri (Lebanon), Pille Teppand (Estonia), and Leonid Voronkov (Ukraine).

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Conflict of interest: G.B. reports, outside the submitted work, personal fees (Boehringer Ingelheim, Pfizer, AstraZeneca, and Novo Nordisk). B.C. is the ESC Board Member and Immediate Past President and reports, outside the submitted work, in kind support (Roche Diagnostics and iRhythm) for research projects and lecture fee (Menarini Foundation). A.C. reports, outside the submitted work, honoraria and/or lecture fees (AstraZeneca, Bayer, Boehringer Ingelheim, Menarini, Novartis, Nutricia, Servier, Vifor, Abbott, Actimed, Arena, Cardiac Dimensions, Corvia, CVRx, Enopace, ESN Cleer, Faraday, Gore, Impulse Dynamics, Respicardia, Viatrix). C.P.G. reports, outside the submitted work, consultancy (AstraZeneca, Bayer, Bristol Myers Squibb, Boehringer-Ingelheim, Chiesi, Daiichi Sankyo, Menarini), speaker fees (AstraZeneca, Menarini, Raisio Group, Wondr Medical, Zydus), editorship (Deputy Editor: European Heart Journal Quality of Care and Clinical Outcomes, Oxford University Press), grants (British Heart Foundation, National Institute for Health Research, Horizon 2020, Abbott Diabetes, Bristol Myers Squibb), Advisory Board (Amgen, Bayer, Bristol Myers Squibb, Boehringer-Ingelheim, Chiesi, Daiichi Sankyo, Menarini), leadership (NICE Indicator Advisory Committee, Chair ESC Quality Indicator Committee). L.H.L. reports, outside the submitted work, research grants (AstraZeneca, Vifor, Boston Scientific, Boehringer Ingelheim, Novartis), consulting fees (Merck, Vifor Pharma, AstraZeneca, Bayer, Pharmacosmos, MedScape, Sanofi, Lexicon, Myokardia, Boehringer Ingelheim, Servier), lecture fees (Abbott, MedScape, Radcliffe, AstraZeneca, Novartis, Bayer, TMA Academy, Boehringer Ingelheim, Orion Pharma), and stock (AnaCardio). G.R. reports, outside the submitted work, personal fees (Menarini, Vifor, AstraZeneca, Servier, Cytokinetics).

Data availability

The data underlying this article are available in the article and in its online supplementary material.

Appendix

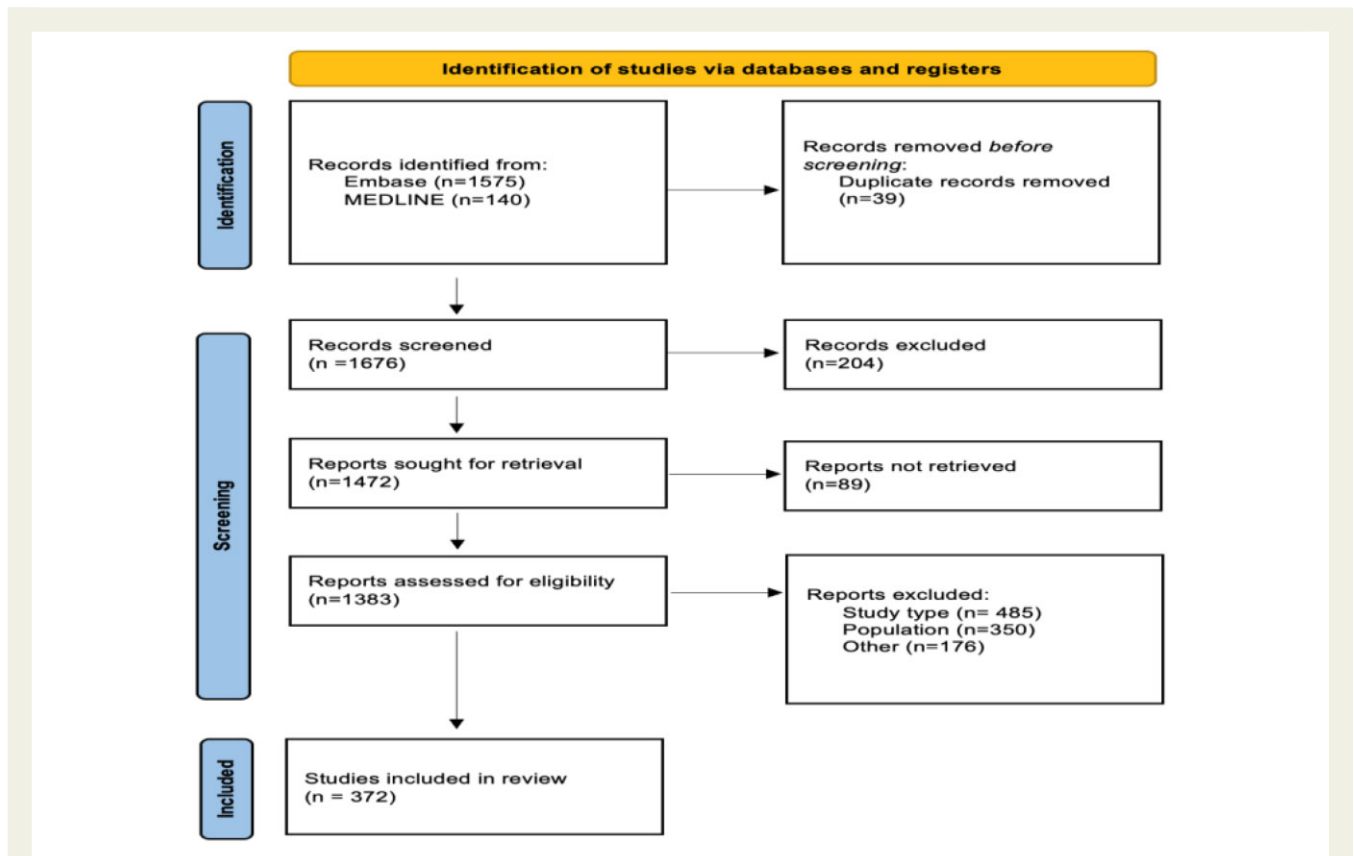


Figure A1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart for the systematic review.

Presentation details Hide ^

Type of encounter ⓘ
 Acute hospital admission Planned hospital admission

Admission/Visit date ⓘ
2021-10-12

NYHA class ⓘ
 NYHA class I NYHA class II NYHA class III NYHA class IV Unknown

Killip class ⓘ
 Killip I Killip II Killip III Killip IV Unknown

Systolic blood pressure (mmHg) ⓘ
 Unknown

Heart rate (bpm) ⓘ
 Unknown

Figure A2 Sample of the variables in the presentation details domain.

In-hospital management Hide ^

Loop diuretics ⓘ

No Yes Unknown

Heart transplant ⓘ

No Yes Unknown

In-hospital implantation of cardiac therapeutic or monitoring devices ⓘ

No

Transvenous permanent pacemaker

Leadless pacemaker

Transvenous ICD

Subcutaneous ICD

CRT-P

CRT-D

Cardiac contractility modulation device

Baroreflex stimulation device

Ventricular assist device

CardioMEMS

Implantable loop recorder

Other

Unknown

Figure A3 Sample of the variables in the in-hospital management domain.

Table A1 Names and affiliations of the EuroHeart-Heart Failure Working Group members

Name	Affiliation
Suleman Aktaa	<ul style="list-style-type: none"> Leeds Institute of Cardiovascular and Metabolic Medicine, University of Leeds, Leeds, UK. Leeds Institute for Data Analytics, University of Leeds, Leeds, UK. Department of Cardiology, Leeds Teaching Hospitals NHS Trust, Leeds, UK. Data Science Group of EuroHeart.
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Andrew Coats	<ul style="list-style-type: none"> University of Warwick, Coventry, UK. President, Heart Failure Association of the European Society of Cardiology.
Chris P. Gale	<ul style="list-style-type: none"> Leeds Institute of Cardiovascular and Metabolic Medicine, University of Leeds, Leeds, UK. Leeds Institute for Data Analytics, University of Leeds, Leeds, UK. Department of Cardiology, Leeds Teaching Hospitals NHS Trust, Leeds, UK. Data Science Group of EuroHeart.
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Continued

Table A1 Continued

Name	Affiliation
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Table A2 Terms used for the systematic review of the literature for the development of the EuroHeart-Heart Failure Data Standards

Database: Embase <1996 to 2021 Week 2>
10 January 2021

- 1 *heart failure/or acute heart failure/or *forward heart failure/or *systolic dysfunction/(114036)
- 2 *Congestive Cardiomyopathy/or exp *Congestive Heart Failure/(39070)
- 3 exp Heart Failure/or exp Ventricular Dysfunction/or Cardiac Output, Low/(504308)
- 4 ((heart or cardiac or myocardial) adj2 (failure or decompensation)).ti. (111005)
- 5 ((congestive or acute or decompensat\$) adj2 'heart failure').ti, ab. (63281)
- 6 ((ventricular or ventricle\$) adj2 (failure or insufficient\$ or dysfunction\$)).ti, ab. (45479)
- 7 ((heart* or cardia* or myocard*) adj3 (fail* or decompensat* or edema* or incompetence or insufficiency)).ti, ab. (299001)
- 8 or/1-7 (565730)
- 9 register/(112003)
- 10 disease registry/(16572)
- 11 registry.ti, ab. (202448)
- 12 registries.ti, ab. (40590)
- 13 register*.ti, ab. (275434)
- 14 database*.ti, ab. (742783)
- 15 exp cohort analysis/(718390)
- 16 exp longitudinal study/(150911)
- 17 exp prospective study/(675541)
- 18 exp follow-up/(1636601)
- 19 cohort\$.tw. (1120767)
- 20 (random\$ or placebo\$ or single blind\$ or double blind\$ or triple blind\$).ti, ab. (1644687)

Continued

Table A2 Continued

Database: Embase <1996 to 2021 Week 2>
10 January 2021

- 21 or/9-20 (5059786)
- 22 exp common data elements/(387)
- 23 core data elements/(0)
- 24 exp nomenclature/(45465)
- 25 (data adj3 (harmoni? * or standard* or defin*)).ti, ab. (41970)
- 26 (data adj3 (element* or field* or variable*)).ti, ab. (33473)
- 27 data aggregation/(240)
- 28 big data/(3463)
- 29 data base/(235598)
- 30 clinical data repository/(1224)
- 31 data extraction/(17304)
- 32 data consistency/(234)
- 33 data collection method/(5237)
- 34 or/22-33 (372747)
- 35 (random sample\$ or random digit\$ or random effect\$ or random survey or random regression).ti, ab. not exp randomized controlled trial/(122020)
- 36 news/or exp historical article/or Anecdotes as Topic/(35146)
- 37 (book or conference paper or review).pt. not exp randomized controlled trial/(2833116)
- 38 meta-analysis/(215159)
- 39 'systematic review'/or 'review'/or 'systematic review (topic)'/ (2373930)
- 40 Congresses as Topic/(81476)
- 41 case report/or case study/(1932078)
- 42 (editorial or letter or comment*).ti. (219574)
- 43 (animal\$ not human\$).sh, hw. (2966520)
- 44 (animals/not humans/) or exp Animals, Laboratory/or exp Animal

Continued

Table A2 Continued

**Database: Embase <1996 to 2021 Week 2>
10 January 2021**

Experimentation/or exp Models, Animal/or exp Rodentia/or (rat or rats or mouse or mice).ti. (3598187)

45 or/35–44 (9129520)

46 8 and 21 and 34 (9462)

47 46 not 45 (7835)

48 limit 47 to English language (7773)

49 limit 48 to dd = 20160101–current (1575)

**Database: Ovid MEDLINE(R) ALL <1946 to January 09, 2021>
10 January 2021**

1 heart failure/or acute heart failure/or *forward heart failure/or *systolic dysfunction/(98350)

2 *Congestive Cardiomyopathy/or exp *Congestive Heart Failure/(112088)

3 exp Heart Failure/or exp Ventricular Dysfunction/or Cardiac Output, Low/(164429)

4 ((heart or cardiac or myocardial) adj2 (failure or decompensation)).ti. (78454)

5 ((congestive or acute or decompensat\$) adj2 'heart failure').ti, ab. (49761)

6 ((ventricular or ventricle\$) adj2 (failure or insufficient\$ or dysfunction\$)).ti, ab. (31951)

7 ((heart* or cardia* or myocard*) adj3 (fail* or decompensat* or edema* or incompetence or insufficiency)).ti, ab. (205332)

8 or/1–7 (284496)

9 register/(6642)

10 registry.ti, ab. (122780)

11 registries.ti, ab. (27497)

12 register*.ti, ab. (219437)

13 database*.ti, ab. (511239)

14 exp cohort analysis/(2172662)

15 exp longitudinal study/(147456)

16 exp prospective study/(584745)

17 cohort\$.tw. (675517)

18 (random\$ or placebo\$ or single blind\$ or double blind\$ or triple blind\$).ti, ab. (1334546)

19 or/9–18 (4064979)

20 exp common data elements/(118)

21 (data adj3 (harmoni? * or standard* or defin*)).ti, ab. (30832)

22 (data adj3 (element* or field* or variable*)).ti, ab. (27135)

23 data aggregation/(47)

24 big data/(1548)

25 data collection method/(90509)

Continued

Table A2 Continued

**Database: Embase <1996 to 2021 Week 2>
10 January 2021**

26 Electronic Data Processing/(13290)

27 Routinely Collected Health Data/(29)

28 Data Collection/(90509)

29 Data Warehousing/(171)

30 or/20–29 (160215)

31 (random sample\$ or random digit\$ or random effect\$ or random survey or random regression).ti, ab. not exp randomized controlled trial/(101589)

32 news/or exp historical article/or Anecdotes as Topic/(610698)

33 (book or conference paper or review).pt. not exp randomized controlled trial/(2825568)

34 meta-analysis/(137155)

35 'systematic review'/or 'review'/or 'systematic review (topic)'/ (2888784)

36 Congresses as Topic/(28033)

37 case report/or case study/(2192999)

38 (editorial or letter or comment*).ti. (202576)

39 (animal\$ not human\$).sh, hw. (4815343)

40 (animals/not humans/) or exp Animals, Laboratory/or exp Animal Experimentation/or exp Models, Animal/or exp Rodentia/or (rat or rats or mouse or mice).ti. (5811211)

41 or/31–40 (11326251)

42 8 and 19 and 30 (551)

43 42 not 41 (447)

44 limit 43 to English language (432)

45 limit 44 to dt = 20160101–20210110 (140)

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