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ORIGINAL ARTICLE

Data standards for atrial fibrillation/flutter and catheter ablation: the European Unified Registries for Heart Care Evaluation and Randomized Trials (EuroHeart)

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Aims Standardized data definitions are essential for monitoring and assessment of care and outcomes in observational studies and randomized controlled trials (RCTs). The European Unified Registries for Heart Care Evaluation and Randomized Trials (EuroHeart) project of the European Society of Cardiology aimed to develop contemporary data standards for atrial fibrillation/flutter (AF/AFL) and catheter ablation.

Methods and results We used the EuroHeart methodology for the development of data standards and formed a Working Group comprising 23 experts in AF/AFL and catheter ablation registries, as well as representatives from the European Heart Rhythm Association and EuroHeart. We conducted a systematic literature review of AF/AFL and catheter ablation registries and data standard documents to generate candidate variables. We used a modified Delphi method to reach a consensus on a final variable set. For each variable, the Working Group developed permissible values and definitions, and agreed as to whether the variable was mandatory (Level 1) or additional (Level 2). In total, 70 Level 1 and 92 Level 2 variables were selected and reviewed by a wider Reference Group of 42 experts from 24 countries. The Level 1 variables were implemented into the EuroHeart IT platform as the basis for continuous registration of individual patient data.

[†] Developed in collaboration with the European Heart Rhythm Association (EHRA) of the European Society of Cardiology

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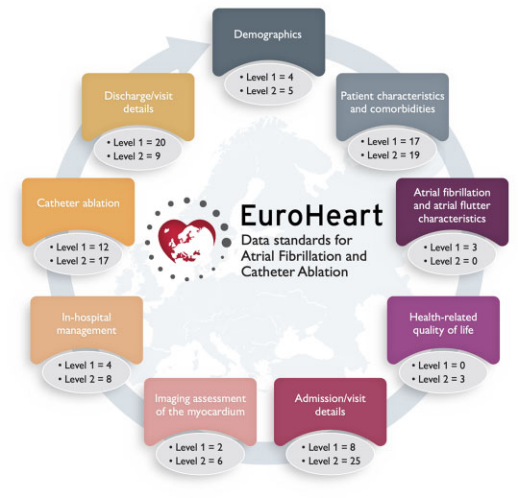
Conclusion By means of a structured process and working with international stakeholders, harmonized data standards for AF/AFL and catheter ablation for AF/AFL were developed. In the context of the EuroHeart project, this will facilitate country-level quality of care improvement, international observational research, registry-based RCTs, and post-marketing surveillance of devices and pharmacotherapies.

Graphical Abstract EuroHeart 2022 data standards for atrial fibrillation/flutter and catheter ablation



Keywords Data standards • Data variables • Atrial fibrillation • Atrial flutter • Catheter ablation • EuroHeart

Introduction

Atrial fibrillation (AF) and atrial flutter (AFL) are the most frequently sustained cardiac arrhythmias in adults and pose a major healthcare and economic burden on individuals and societies.[1,2] About 3% of the adult population have AF/AFL and it is estimated that one out of three European individuals over the age of 55 years will be affected by AF/AFL during their lifetime.[3–5] There are differences in the management and outcomes of patients with AF/AFL within and among countries, depending not only on variability in resources and competence but also on an almost universal lack of monitoring of standards of care in the broad AF/AFL populations.[6–8] Currently, information on methods for AF/AFL diagnosis, treatment and outcomes is based on randomized controlled trials (RCTs) and limited information from scientific reports from registries, administrative databases and electronic health care records (EHRs).[1] Notably, comparisons of data over time and between studies or countries are compounded by variations in the data variables collected and their definitions.[9]

The adoption of standardised data variables and definitions is necessary for reliable assessment and comparison of quality of care within and among countries, international observational studies, RCTs, and post-marketing surveillance of devices and pharmacotherapies.[10] Currently, there are no pan-European data standards for AF/AFL and catheter ablation that reflect contemporary clinical practice guidelines and are applicable to European healthcare systems. The 2004 American College of Cardiology (ACC)/American Heart Association (AHA) Key Data Elements and Definitions for AF provide a catalogue of data variables that describe care delivery and outcomes for patients with AF.[9] However, whilst the document defines a comprehensive list of 149 data variables, there is no hierarchical specification as to which variables may be of greater importance—potentially limiting their utility in clinical practice.[9] Moreover, those data standards were developed in accordance with the North American clinical practice guidelines and have not since been updated. The 2004 Cardiology Audit and Registration Data Standards (CARDS) project, which was the first European initiative to develop data standards for cardiovascular disease, focussed on acute coronary syndrome (ACS), percutaneous coronary intervention (PCI), and clinical electrophysiology, but not AF/AFL.[11]

The European Unified Registries for Heart Care Evaluation and Randomized Trials (EuroHeart) is a project initiated and supported by the European Society of Cardiology (ESC) that aims to improve the quality of cardiovascular care through the capture of individual patient data using standardized variables and a common IT infrastructure (*Figure 1*).[12] The aim of EuroHeart is to collect longitudinal data to provide information about the trajectory of patient care and outcomes over time and has published international data standards for ACS, PCI, and heart failure.[13,14] Here, we present the EuroHeart data standards for AF/AFL and catheter ablation, which were developed in collaboration with the European Heart Rhythm Association (EHRA) of the ESC.

Methods

EuroHeart methodology: the five-step process

We adopted the EuroHeart five-step process for the development of data standards for cardiovascular diseases.[15] This includes the (i) identification of clinical cardiovascular domains for data standards development; (ii) conduction of a systematic literature review to identify candidate variables and definitions; (iii) selection and prioritisation of variables and definitions by a domain-specific Working Group; (iv) validation of the variables and definitions by a domain-specific Reference Group; and (v) implementation of the developed data standards into the EuroHeart online IT platform.[16]

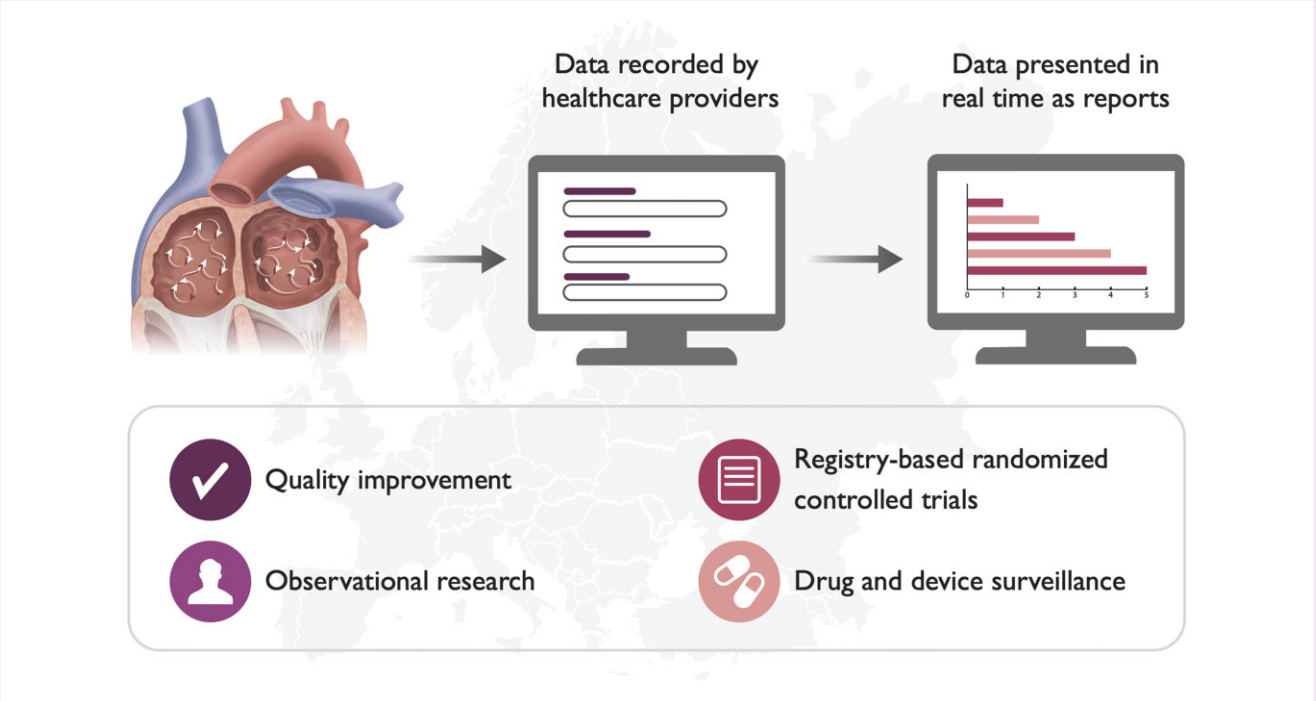


Figure 1 European Unified Registries for Heart Care Evaluation and Randomized Trials data standards and aims of the European Unified Registries for Heart Care Evaluation and Randomized Trials project. EuroHeart, European Unified Registries for Heart Care Evaluation and Randomized Trials

EuroHeart data standards

In EuroHeart, there are three categories of variables: Level 1 to 3.[16] Level 1 variables are 'mandatory'. They are relevant to the public reporting of quality of care, risk stratification, case-mix adjustment, and outcome evaluation. 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 additional measures that may prove useful in selected areas or circumstances, but which do not need to be universally available. They complement quality assessment and may have a role in observational or randomized clinical research. Level 2 variables are defined in the EuroHeart data standard documents but are not routinely implemented on the EuroHeart IT platform. Finally, the EuroHeart platform also allows the addition of a third set of variables (Level 3) that can be centre- or country-specific and required for national or local studies or a specific quality improvement project. Level 3 variables are not defined or programmed by EuroHeart.

Data Science Group, Working Group, and Reference Group composition

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

A Working Group for the development of the 2022 EuroHeart data standards for AF/AFL and catheter ablation was formed including 23 members representing 11 countries. The domain-specific Working Group comprised representatives from EHRA, selected AF/AFL and catheter ablation registry experts and members from the EuroHeart Data Science Group. Names of the members of the Working Group and their affiliations are provided in the Appendix (*Table A1*).

The Reference Group included 42 international experts in AF/AFL and catheter ablation representing 24 ESC-member countries, patient representatives, and data analysts. The Group reviewed the selected variables and provided their feedback. Names of members of the Reference Group members are provided in the Acknowledgments.

Systematic literature review and other data sources

A systematic literature review was conducted by the EuroHeart Data Science Group. The scope of the review was to identify potential variables from existing registries and data standard documents related to AF/AFL and/or catheter ablation. Using Embase and Medline, we included peer-reviewed documents that defined at least one data variable relevant to AF/AFL and/or catheter ablation between 1 January 2016 and 15 April 2021 (Appendix *Table A2*). The included studies were reviewed by two independent authors (G.B. and S.A.) who identified potential data variables relevant to AF/AFL and extracted these variables alongside their definitions. Disagreements were resolved through discussion. These variables were added to other variables from existing clinical practice guidelines, quality indicators, and the data dictionaries of existing AF and catheter ablation registries, and formed the basis for the voting process.[1,8,9,17–20]

Consensus development and selection of variables and definitions

The Working Group decided that the scope of the EuroHeart AF/AFL registry was to capture the continuum of AF, AFL, and catheter ablation care delivery across the range of healthcare settings (e.g. in-patient and out-patient) and clinical contexts (e.g. new onset and prevalent AF/AFL). It was agreed that the data standards should be broadly applicable and enable interoperability between clinical registries, quality-of-care improvement projects, EHRs, and clinical trial protocols.

From the outset, the goal of the Working Group was to strike a balance between developing a focused yet comprehensive data standards document. The Working Group reviewed the candidate variables derived from the literature and decided on the inclusion of the variables and whether they were Level 1 or Level 2 using a modified Delphi method.

Two rounds of voting were conducted, and each Working Group member was asked whether the proposed variables should be included as Level 1, included as Level 2, or excluded. An agreement of 75% was needed to include the variable in the dataset. The candidate variables from the systematic review that didn't meet the inclusion criteria during the first voting round but were deemed important by the Working Group in the subsequent meetings were voted upon in a second voting round.

To standardise the voting, the EuroHeart criteria for data standards (importance, evidence base, validity, reliability, feasibility, and applicability) were shared with the Working Group in the initial phases of the process.[16] Once the final dataset was selected, the Working Group developed permissible values and definitions for the variables. The work of the Working Group was accomplished during eight virtual peer-to-peer meetings and extensive written correspondence.

Review of the data standards

Following the modified Delphi voting, the data standards were shared with an external Reference Group that reviewed and provided feedback on the proposed data variables, definitions, and permissible values. Narrative and written comments were considered by the Data Science Group and Working Group with variables modified accordingly.

Implementation into the EuroHeart IT platform

The final set of data variables, definitions, and permissible values were transferred to the Registry Technology Group of the EuroHeart project as a basis for programming into the EuroHeart IT platform. All Level 1 variables were implemented into the IT platform. For each variable, the Data Science Group provided the IT team with specifications for data entry and permissible ranges for numerical variables to facilitate consistent data entry.

Results

The literature review retrieved 776 articles, of which 265 (34%) articles met the inclusion criteria and were included as the basis for extracting 376 candidate variables (Appendix *Figure A1*). The modified Delphi process resulted in the selection of 162 variables in the EuroHeart AF/AFL and catheter ablation data standards across nine sections of AF/AFL care (Graphical abstract). This comprised 70 Level 1 (mandatory) variables (58 for AF/AFL and 12 for catheter ablation) and 92 Level 2 (additional) variables (75 for AF/AFL and 17 for catheter ablation) (Supplementary material online, *Table S1–S2*).

Demographics

The demographics section collects patient details such as identification number, date of birth, and sex (Supplementary material online, *Table S1*). Notably, the section is fully aligned with the other EuroHeart data standards (ACS, PCI, and heart failure) in order to minimise the burden of data collection for time-independent variables for patients enrolled in >1 EuroHeart registry. Whilst this section captures patient-identifiable information to allow linkage with other data sources (e.g. death registry), these data are kept locally and not shared with the EuroHeart Data Science Group to maintain patient confidentiality. At the centre- or country level, the national unique identification number may be used in the EuroHeart registries. For the countries without unique identification numbers, the EuroHeart IT platform generates for each enrolled patient a unique code that can be used across the different EuroHeart registries.

Patient characteristics and comorbidities

The Level 1 variables in this section collect data about patient sex, anthropometric characteristics (e.g. weight and height), and past medical history (e.g. diabetes mellitus and prior stroke) at the time of hospital admission or outpatient visit (Supplementary material online, *Table S1*). The selection criteria for the Level 1 variables in this section were determined by variables frequently used in AF/AFL and catheter ablation studies and those important for risk adjustment such that biased estimates of associations when evaluating variations in performance and treatment may be minimized. Many of the variables in this section are also readily available in average medical health records including the components of the CHA_2DS_2-VASc score (congestive heart failure, hypertension, age, diabetes mellitus, stroke/transient ischaemic attack/thromboembolism history, vascular disease history, and sex).[21] Additional characteristics and comorbidities were selected as Level 2 variables (Supplementary material online, *Table S2*).

Atrial fibrillation and atrial flutter characteristics

This section collects information about the duration and type of AF and/or AFL at the time of clinical encounter and is important for disease characterisation (Supplementary material online, *Table S1*). Many patients will likely have received a diagnosis of AF and/or AFL prior to initial registration. However, the registry aims to capture and permit the inclusion of patients with a variety of AF/AFL states, including new-onset and established arrhythmia.

Health-related quality of life

Patient reported outcome measures (PROMs), such as symptom burden, functional status, and health-related QoL (HRQoL) are important prognostic elements which inform patients, healthcare providers, and policymakers about a patient's self-perceived morbidity.[22] Numerous generic and disease-specific HRQoL tools are available [e.g. European QoL-5 dimensions (EQ-5D) and AF effect on QoL (AFEQT)].[23–25] However, HRQoL is a difficult concept to measure, and the assessment is often a complex undertaking requiring multiple measures to capture subjectivity and multidimensionality.[26] As such and given the concerns about the feasibility of measuring HRQoL routinely in practice, the EuroHeart AF/AFL and catheter ablation data standards include variables about whether the HRQoL was assessed, which tool was used and the results of the measurement as Level 2 variables (Supplementary material online, *Table S2*). With appropriate resources and copyright license agreement, specific HRQoL questionnaires may be implemented into the registry as Level 3 variables.

Admission/visit details

The admission/visit details section captures information about the type (in-patient or out-patient) and context (acute or planned) of the clinical encounter, as well as details about patient's current symptoms (EHRA score), biomarker levels (including haemoglobin, creatinine), and clinical findings at the time of assessment (such as ECG parameters) (*Figure 2*). These variables are often readily available and have prognostic value for individualised risk assessment and for tailoring of treatment strategies (Supplementary material online, *Table S1*).[27,28] Medical therapy prior to the clinical encounter is part of the admission/visit details section and is included as Level 2 variables because of concerns among the Working Group members about the feasibility of collecting such information (Supplementary material online, *Table S2*).

Imaging assessment of the myocardium

In this section, the Level 1 variables comprise the findings of the most recent evaluation of the left ventricular ejection fraction and the left atrial volume (Supplementary material online, *Table S1*). Given their prognostic significance and importance for AF/AFL management,

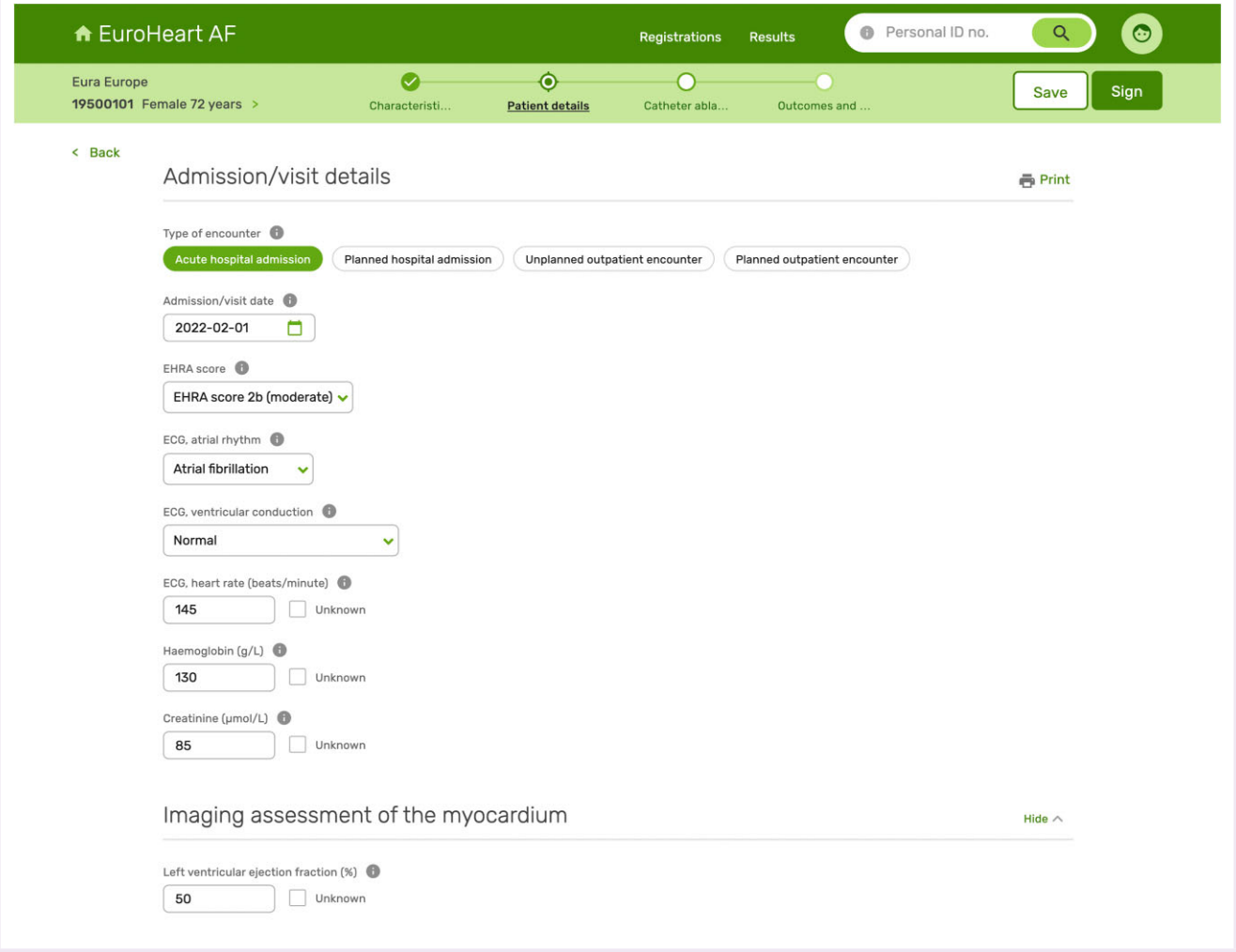


Figure 2 European Unified Registries for Heart Care Evaluation and Randomized Trials IT platform and collection form for atrial fibrillation/flutter and catheter ablation. EuroHeart, European Unified Registries for Heart Care Evaluation and Randomized Trials.

these variables were selected as Level 1 by the Working Group.[29,30] Other variables such as diastolic dysfunction, hypertrophic cardiomyopathy and right atrial volume were included as Level 2 variables (Supplementary material online, *Table S2*).

In-hospital management

The in-hospital management section includes information about the delivery of patient care during hospital admission or clinic visit. Here, the Level 1 variables capture data about cardioversion (including electrical or pharmacologic approaches) and left atrial appendage closure/exclusion (Supplementary material online, *Table S1*). In addition, other variables relevant to the management of the patient during the hospital stay were included at Level 2 (Supplementary material online, *Table S2*).

Catheter ablation

Presently, catheter ablation for AF and AFL is the most common cardiac ablation procedure in Europe.[31] This section collects information about AF/AFL catheter ablation including procedural indication, approach and lesion location, as well as energy source and the outcome of the ablation (Supplementary material online, *Table S1*). Variables that collect greater detail about the procedure are provided as Level 2 (Supplementary material online, *Table S2*).

Discharge/visit details

The discharge/visits section collects information about the outcomes of care (including peri-procedural and in-hospital events), the hospital discharge date and information such as ECG findings at the time of discharge and planned treatment strategies (i.e. rhythm vs. rate control). For risk stratification, the CHA_2DS_2-VASc score is automatically calculated to allow the utilisation of collected data in predicting stroke risk (Supplementary material online, *Table S1*).[21]

The final part of the section is dedicated to the medications prescribed at the time of discharge from hospital. Many of the medications in this section are recommended by the current ESC guidelines for the diagnosis and management of AF and tally with the ESC quality indicators for AF.[1,17] For medications commonly prescribed to patients with AF/AFL (e.g. oral anticoagulants), information not only about the class of drug, but also about the generic name and the dose is captured (Supplementary material online, *Table S1–S2*).[32,33]

Discussion

The recording of standardised and high-quality data underpins the process by which clinical care may be evaluated and improved.[10] A lack of monitoring of care processes and outcomes, compounded by the absence of contemporary internationally defined data standards, has contributed to variability in the detection, management, and outcomes of AF/AFL across Europe.[6,7] This has also resulted in inefficiently delivered cardiovascular studies.[34] By means of a structured methodology, and in collaboration with EHRA, the EuroHeart project of the ESC has defined a catalogue of 70 Level 1 and 92 Level 2 AF/AFL and catheter ablation variables with accompanying definitions and permissible values. These data standards have been implemented in the interactive EuroHeart IT platform to facilitate efficient longitudinal data collection and quality improvement, observational and registry-based randomized research and post-marketing surveillance of devices and pharmacotherapies. These structured data standards may also be implemented by other registration systems, case report forms, or EHRs and will facilitate national and international collaborations on quality development and scientific studies in patients with AF/AFL.

It is recognised that AF/AFL has become a major public health problem.[3] It is estimated that approximately 3% of the adult population has AF/AFL, with the incidence and prevalence estimated to increase with an accompanying surge in clinical and public health costs and novel approaches to its detection.[35] However, the true prevalence of AF/AFL is unknown, probably due to estimates derived from populations with varying risk and owing to asymptomatic AF/AFL often being undiagnosed.[3,36] The emergence of novel medications (e.g. direct oral anticoagulants) and treatment strategies for AF/AFL has improved outcomes, but patients with AF/AFL are still at high risk of mortality, morbidity and poor HRQoL.[37] The growing health burden of AF/AFL shapes the need to develop systems for continuous capture of AF/AFL data and to monitor the quality of care. Such systems may also be used to deliver high-quality, yet cost-effective research particularly if accompanied by an integrated IT platform that facilitates data collection, analysis and reporting. Until now, the lack of harmonized data standards for AF/AFL and catheter ablation has limited the opportunity to combine data from different registries and thus, conduct of international comparative analyses and large-scale collaborations.

The EuroHeart AF/AFL and catheter ablation data standards extend the literature by providing a contemporary international perspective for AF/AFL management and incorporate the processes of AF care proposed by the ESC guidelines.[1] Despite the development of harmonized definitions for AF in the US, the ACC/AHA Key Data Elements and Definitions for AF have not been fully adopted by the ACC's AFib Ablation Registry and the AHA's Get With the Guidelines (GWTG) AF Registry, resulting in heterogeneity in the methods by which the AF variables are defined and collected.[9,18,19] In addition, these efforts provide a North American perspective to AF care which may differ from Europe's, stressing the need for pan-European data standards for AF/AFL.[9,18,19]

Although the EuroHeart AF/AFL data standards share some similar variables with those defined by the ACC and the AHA, there are important differences. First, the EuroHeart variables are harmonised across various cardiovascular domains including ACS, PCI, heart failure and transcatheter aortic valve implantation (TAVI). This provides means for data pooling from different resources when conducting research studies. Second, the EuroHeart AF/AFL and catheter ablation data standards have two levels of variables based on importance, with only the mandatory variables implemented onto an IT platform. By contrast, the ACC/AHA data standards have not established a hierarchy based on the importance of the variables and mandate the collection of around 150–200 variables for every patient (compared to 70 Level 1 variables in the EuroHeart AF/AFL and catheter ablation registry).[9,18,19] For Europe, the CARDS project in 2004 defined data variables for clinical electrophysiology, but these variables have since then not been updated to reflect the advances in catheter ablation and medical management for AF/AFL.[11]

The EuroHeart data standards for AF/AFL and catheter ablation have been developed in collaboration with EHRA and with the involvement of AF/AFL experts and registry leaders from 11 countries. A Reference Group involved members from 24 countries to provide feedback in collaboration with EHRA, the ESC Working Group on Thrombosis, the ESC Patient Forum, the Association of Cardiovascular Nursing and Allied Professions (ACNAP), the ESC Committee for Young Cardiovascular Professionals, the Working Group on Myocardial and Pericardial Diseases Young in Career Group, and the EURObservational Research Programme (EORP). The level of engagement of international experts highlights the mission of EuroHeart, which is to provide means for capturing structured data to improve the quality of patient care and to support the generation of representative observational data.[12]

Individual patient data collected by participating EuroHeart centres will be stored in the country of collection under the responsibility of national or regional registry centres, according to the local law and data protection regulations. Signed informed consent will not be required for data collection for quality development in most countries. Only de-identified and aggregated data (i.e. no individual patient data) may be shared by participating countries for pre-defined statistical analysis. For prospective registry-based RCTs or drug and device monitoring initiatives, ethical approval, and informed consent from patients will be required as for any other clinical investigation.

We recognise the limitations of the EuroHeart methodology for data standards development. Despite basing the data standards on the results from a systematic review, the final variables, definitions, and permissible values were selected by a Working Group based on expert opinion and this may incur bias. Nonetheless, we feel that the inclusiveness of the Working Group (which comprised experts from many European countries with experience in national and international registries, quality improvement projects and observation and randomized research) provided a robust and transparent framework. We also formed an international Reference Group, including patient representatives and computer scientists, to 'check and challenge' and therefore enhance the robustness and validity of our approach. Even so, future Working Groups may benefit from being wider and inclusive of pharmacists, primary care physicians, health service researchers, and quality improvement specialists. The EuroHeart data standards for AF/AFL and catheter ablation have been implemented into the EuroHeart IT platform as a basis for continuous longitudinal data entry. However, the data standards have not been translated into computer-based language structures [e.g. Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)].[38] Standardized computer-based language structures are important for the electronic exchange of data between IT systems (e.g. registries and EHRs), but the linkage of variables and data ontologies is currently beyond the scope of this project. The data standards proposed in this document are based on the evidence available at the time of development. Future updates may be required as new evidence becomes available.

Conclusions

This document presents the first EuroHeart data standards for AF/AFL and catheter ablation which have been developed in collaboration with the EHRA of ESC using a standardized methodology. In total, 162 variables have been proposed as either mandatory (Level 1) or additional (Level 2), with the Level 1 variables been implemented into the EuroHeart IT platform. Once adopted, the data standards will facilitate country-level quality of care improvement, observational and

registry-based randomized research and post-marketing surveillance of devices and pharmacotherapies.

Supplementary material

Supplementary material is available at *European Heart Journal–Quality of Care and Clinical Outcomes* online.

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L.F., reports, outside this work, consultant or speaker activities for AstraZeneca, Bayer, BMS/Pfizer, Boehringer Ingelheim, Medtronic, Novartis, Novo, XO, and Zoll.

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F.S., reports, outside this work, lecture/speaker fees from Abbott, Bayer, Biosense Webster, Boston Scientific, Inheart, and Microport.

P.S. is advisory board member of Abbott, Biosense Webster, Boston Scientific, and Medtronic.

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All other authors have nothing to declare.

Data availability

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

Appendix

Table A1 Names, countries and affiliations of the European Unified Registries for Heart Care Evaluation and Randomized Trials atrial fibrillation/flutter and catheter ablation Working Group members. EuroHeart, European Unified Registries for Heart Care Evaluation and Randomized Trials

Name	Country	Affiliation
Suleman Aktaa	United Kingdom	• 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 • EuroHeart Data Science Group
Gorav Batra	Sweden	• Department of Medical Sciences, Cardiology and Uppsala Clinical Research Center, Uppsala University, Uppsala, Sweden • EuroHeart Data Science Group
A. John Camm	United Kingdom	• St George's University, London, UK
Barbara Casadei	United Kingdom	• Division of Cardiovascular Medicine, NIHR Oxford Biomedical Research Centre, University of Oxford, Oxford, UK
Francisco Costa	Portugal	• Cardiology Department, Centro Hospitalar de Lisboa Ocidental EPE Hospital de Santa Cruz, Lisboa, Portugal
Luigi Di Biase	Italy	• Division of Cardiology, Department of Medicine, Albert Einstein College of Medicine/Montefiore Medical Center, New York, USA
David Duncker	Germany	• Hannover Heart Rhythm Center, Department of Cardiology and Angiology, Hannover Medical School, Hannover, Germany
Laurent Fauchier	France	• Service de Cardiologie, Center Hospitalier Universitaire Trousseau et Faculté de Médecine, Université de Tours, Tours, France
Nikolaos Fragakis	Greece	• 3rd Cardiology Department, Hippokration General Hospital, Aristotle University Medical School, Thessaloniki, Greece
Lars Frost	Denmark	• Department of Cardiology, Regional Hospital Central Jutland, Silkeborg, and Department of Clinical Medicine, Aarhus University, Aarhus, Denmark
Chris P Gale	United Kingdom	• 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 • EuroHeart Data Science Group
Ziad Hijazi	Sweden	• Department of Medical Sciences, Cardiology and Uppsala Clinical Research Center, Uppsala University, Uppsala, Sweden
Tord Juhlin	Sweden	• Department of Cardiology, Skåne University Hospital, Lund, Sweden
José Luis Merino	Spain	• Arrhythmia and Robotic Electrophysiology Unit, Hospital Universitario La Paz, Idipaz, Universidad Autonoma, Madrid, Spain
Lluis Mont	Spain	• Hospital Clinic Barcelona, University of Barcelona, Barcelona, Spain • Institut de Recerca Biomèdica August Pi Sunyer (IDIBAPS), Barcelona, Spain • CIBER cardiovascular, Madrid, Spain
Jens Cosedis Nielsen	Denmark	• Department of Cardiology, Aarhus University Hospital and Department of Clinical Medicine, Aarhus University, Aarhus, Denmark
Jonas Oldgren	Sweden	• Department of Medical Sciences, Cardiology and Uppsala Clinical Research Center, Uppsala University, Uppsala, Sweden
Anna Polewczyk	Poland	• Department of Physiology, Patophysiology and Clinical Immunology, Collegium Medicum of The Jan Kochanowski University, Kielce, Poland • Department of Cardiac Surgery, Świętokrzyskie Center of Cardiology, Kielce, Poland
Tatjana Potpara	Serbia	• School of Medicine, University of Belgrade and Intensive Arrhythmia Care, Cardiology Clinic, Clinical Center of Serbia, Belgrade, Serbia
Frederic Sacher	France	• Electrophysiology and Ablation Unit, Bordeaux University Hospital (CHU), LIRYC Institute, Bordeaux, France
Philipp Sommer	Germany	• Clinic for Electrophysiology, Herz- und Diabeteszentrum NRW, Ruhr-Universität Bochum, Bad Oeynhausen, Germany
Roland Tilz	Germany	• Department of Rhythmology, University Heart Center Luebeck, Lübeck, Germany
Lars Wallentin	Sweden	• Department of Medical Sciences, Cardiology and Uppsala Clinical Research Center, Uppsala University, Uppsala, Sweden

Table A2 Terms used for the systematic review of the literature for the development of the EuroHeart atrial fibrillation/flutter and catheter ablation data standards

Database: Embase < 1996 to 2021 Week 18 > Search strategy:	
1.	atrial fibrillation/or atrial flutter/or heart atrium fibrillation/or heart atrium flutter/(170 921)
2.	[(atrial or atrium or auricular) adj1 fibrillation].ti,ab. (138 321)
3.	[(atrial or atrium or auricular) adj1 flutter].ti,ab. (8499)
4.	(AF or Afib or AFl).ti,ab. (88 427)
5.	ablation catheter/or radiofrequency ablation/or thermal ablation delivery device/or ablation therapy/or catheter ablation/or radiofrequency catheter ablation/(88 873)
6.	or/1–5 (274 341)
7.	register/(113 700)
8.	disease registry/(18 055)
9.	registry.ti,ab. (218 444)
10.	registries.ti,ab. (43 352)
11.	register*.ti,ab. (295 098)
12.	database*.ti,ab. (808 323)
13.	exp cohort analysis/(813 073)
14.	exp longitudinal study/(162 841)
15.	exp prospective study/(733 419)
16.	exp follow-up/(1 745 593)
17.	cohort$.tw. (1 220 221)
18.	(random$ or placebo$ or single blind$ or double blind$ or triple blind$).ti,ab. (1 733 043)
19.	or/7–18 (5 407 181)
20.	exp common data elements/(432)
21.	electronic data interchange/(780)
22.	exp nomenclature/(47 033)
23.	[data adj3 (element* or field* or variable*)].ti,ab. (35 573)
24.	[data adj3 (harmoni? * or standard* or defin*)].ti,ab. (42 723)
25.	data aggregation/(300)
26.	big data/(4123)
27.	data base/(239 963)
28.	clinical data repository/(1283)
29.	data extraction/(20 169)
30.	data consistency/(456)
31.	data collection method/(5531)
32.	data interoperability/(405)
33.	or/20–32 (386 130)
34.	(random sample$ or random digit$ or random effect$ or random survey or random regression).ti,ab. not exp randomized controlled trial/(113 617)
35.	news/or exp historical article/or Anecdotes asTopic/(10)
36.	(book or conference paper or review).pt. not exp randomized controlled trial/(2 955 489)
37.	meta-analysis/(236 278)
38.	'systematic review'/or 'review'/(2 470 783)
39.	conference abstract/(1 477 113)
40.	case report/or case study/(2 026 757)
41.	(editorial or letter or comment*).ti. (230 585)
42.	(animal$ not human$).sh,hw. (3 072 660)
43.	(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. (3 735 892)
44.	or/34–43 (10 454 131)
45.	6 and 19 and 33 (4567)
46.	45 not 44 (3569)
47.	limit 46 to English language (3537)
48.	limit 47 to dd = 20 160 101-current (688)

Table A2 Continue

Database: Ovid MEDLINE(R) ALL < 1946 to 14 April, 2021 > Search strategy:	
1.	atrial fibrillation/or atrial flutter/or heart atrium fibrillation/or heart atrium flutter/(67 610)
2.	[(atrial or atrium or auricular) adj3 fibrillation].ti,ab. (81 992)
3.	[(atrial or atrium or auricular) adj3 flutter].ti,ab. (7729)
4.	(AF or Afib or AFl).ti,ab. (48 290)
5.	ablation catheter/or radiofrequency ablation/or thermal ablation delivery device/or ablation therapy/or catheter ablation/or radiofrequency catheter ablation/(37 948)
6.	or/1–5 (138 125)
7.	register/(6643)
8.	registry.ti,ab. (132 710)
9.	registries.ti,ab. (29 290)
10.	register*.ti,ab. (235 428)
11.	database*.ti,ab. (562 321)
12.	exp cohort analysis/(2 315 930)
13.	exp longitudinal study/(156 422)
14.	exp prospective study/(619 714)
15.	cohort$.tw. (737 597)
16.	(random$ or placebo$ or single blind$ or double blind$ or triple blind$).ti,ab. (1 401 762)
17.	or/7–16 (4 315 836)
18.	exp common data elements/(135)
19.	(data adj3 (harmoni? * or standard* or defin*)).ti,ab. (31 306)
20.	[data adj3 (element* or field* or variable*)].ti,ab. (28 880)
21.	Electronic Data Processing/(13 375)
22.	Routinely Collected Health Data/(67)
23.	Database Management Systems/(7719)
24.	Data Collection/(91 381)
25.	Data Warehousing/(196)
26.	[data adj3 (element* or field* or variable*)].ti,ab. (28 880)
27.	[data adj3 (harmoni? * or standard* or defin*)].ti,ab. (31 306)
28.	data aggregation/(61)
29.	big data/(2050)
30.	data collection method/(91 381)
31.	or/18–30 (170 745)
32.	(random sample$ or random digit$ or random effect$ or random survey or random regression).ti,ab. not exp randomized controlled trial/(95 146)
33.	news/or exp historical article/or Anecdotes asTopic/(614 505)
34.	(book or conference paper or review).pt. not exp randomized controlled trial/(2 953 576)
35.	'Systematic Review'/(189 020)
36.	meta-analysis/(155 515)
37.	case report/or case study/(2 256 717)
38.	(editorial or letter or comment*).ti. (213 914)
39.	(animal$ not human$).sh,hw. (4 933 342)
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. (5 963 387)
41.	or/32–40 (11 660 750)
42.	6 and 17 and 31 (240)
43.	42 not 41 (190)
44.	limit 43 to English language (182)
45.	limit 44 to dt = 20 160 101-current (68)

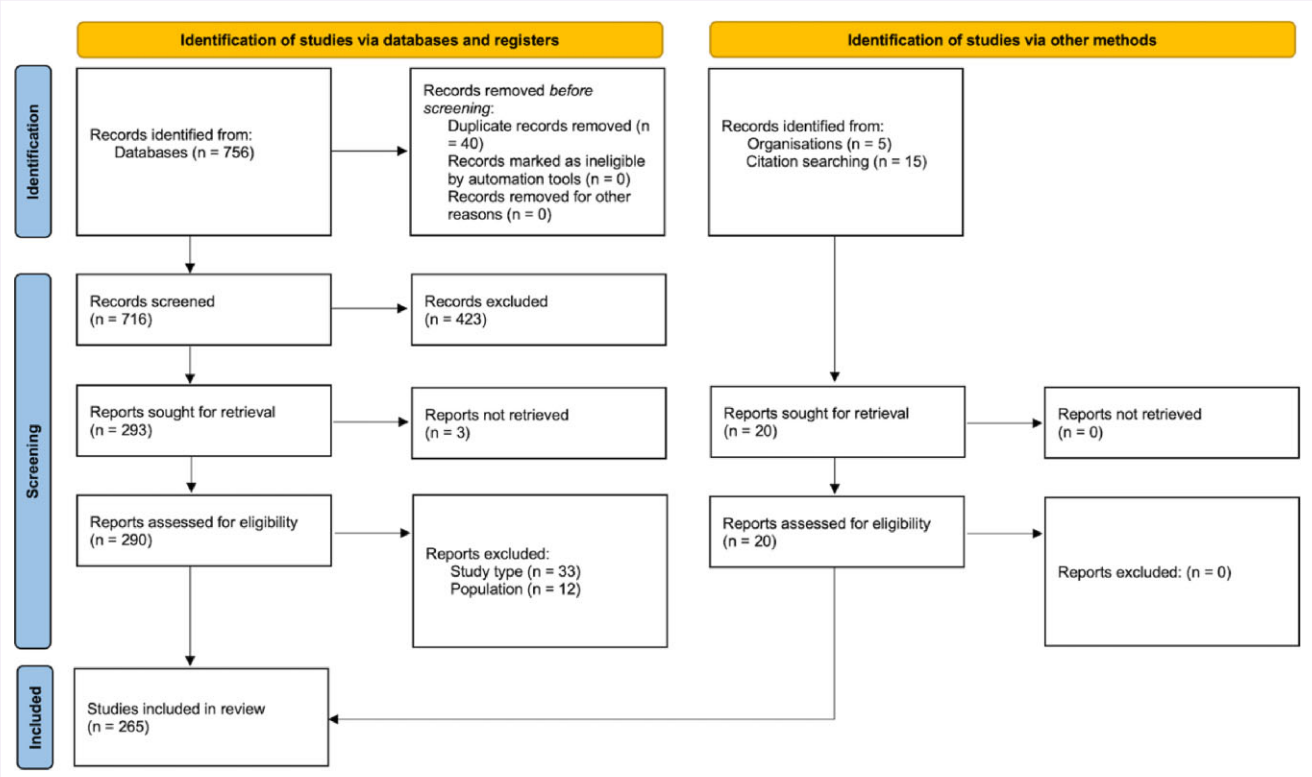

Figure A1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart for the literature review for the development of the European Unified Registries for Heart Care Evaluation and Randomized Trials atrial fibrillation/flutter and catheter ablation data standards. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; EuroHeart, European Unified Registries for Heart Care Evaluation and Randomized Trials.

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