ESC European Society of Cardiology

European Heart Journal (2022) **43**, 2269–2285
https://doi.org/10.1093/eurheartj/ehac133

SPECIAL ARTICLE

Data standards for acute coronary syndrome and percutaneous coronary intervention: the European Unified Registries for Heart Care Evaluation and Randomised Trials (EuroHeart)

In collaboration with the Association of Cardiovascular Nursing and Allied Professions (ACNAP), Association for Acute CardioVascular Care (ACVC), European Association of Percutaneous Cardiovascular Interventions (EAPCI), EURObservational Research Programme (EORP), ESC Patient Forum, ESC Working Group on Thrombosis and ESC Committee for Young Cardiovascular Professionals†

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Received 18 June 2021; revised 14 February 2022; accepted 1 March 2022; online publish-ahead-of-print 5 April 2022

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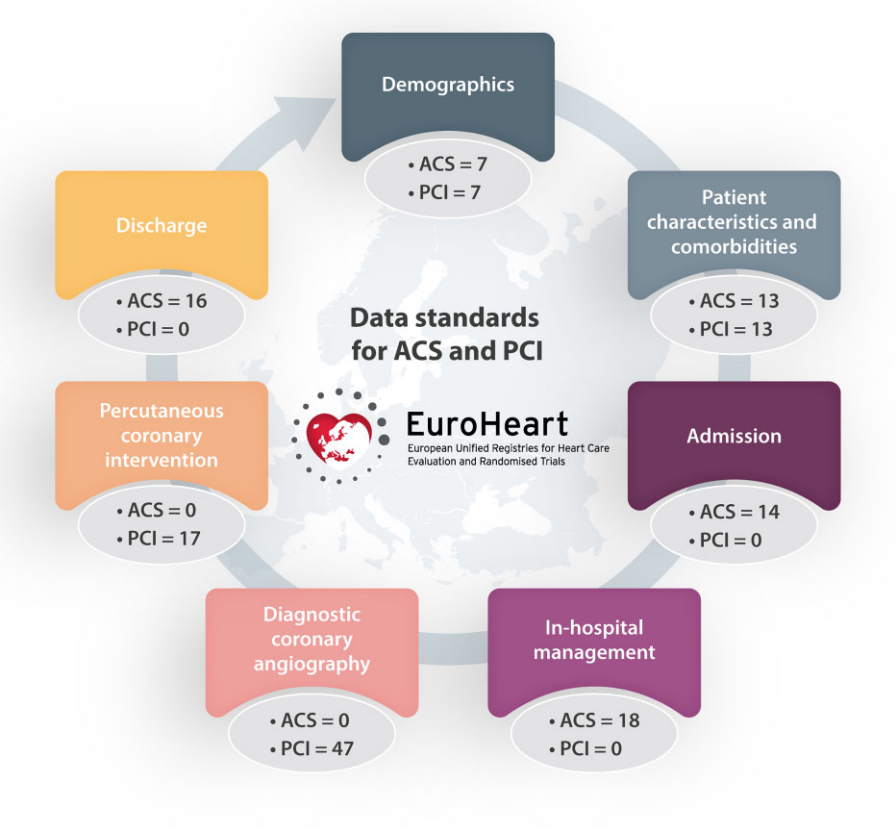

Graphical Abstract Domains of the 2021 EuroHeart acute coronary syndrome and percutaneous coronary intervention data standards with the number of Level 1 (mandatory) variables.

Abstract

Standardized data definitions are essential for monitoring and benchmarking the quality of care and patient outcomes in observational studies and randomized controlled trials. There are no contemporary pan-European data standards for the acute coronary syndrome (ACS) and percutaneous coronary intervention (PCI). The European Unified Registries for Heart Care Evaluation and Randomised Trials (EuroHeart) project of the European Society of Cardiology (ESC) aimed to develop such data standards for ACS and PCI. Following a systematic review of the literature on ACS and PCI data standards and evaluation of contemporary ACS and PCI registries, we undertook a modified Delphi process involving clinical and registry experts from 11 European countries, as well as representatives from relevant ESC Associations, including the European Association of Percutaneous Cardiovascular Interventions (EAPCI) and Acute CardioVascular Care (ACVC). This resulted in final sets of 68 and 84 'mandatory' variables and several catalogues of optional variables for ACS and PCI, respectively. Data definitions were provided for these variables, which have been programmed as the basis for continuous registration of individual patient data in the online EuroHeart IT platform. By means of a structured process and the interaction with major stakeholders, internationally harmonized data standards for ACS and PCI have been developed. In the context of the EuroHeart project, this will facilitate country-level quality of care improvement, international observational research, registry-based randomized trials, and post-marketing surveillance of devices and pharmacotherapies.

Keywords Data standards • Data variables • Data definitions • Acute coronary syndrome • Percutaneous coronary intervention • EuroHeart

Introduction

Standardized data definitions are essential for the reliable investigation of quality of care and outcomes in observational studies and randomized controlled trials. Heterogeneity in such definitions impedes benchmarking and leads to inconsistencies that directly impact the interpretation of clinical studies and the implementation of their findings.[1]

With the advent of large-scale registries, administrative databases, and the widespread use of electronic health records in routine

clinical practice, opportunities to deliver cost-efficient investigator-initiated observational and randomized studies of both devices and pharmacological treatments have been realized.[2–4] Yet, between-country comparisons remain challenging. This is often driven by a variation in the variables and their definitions.[5] This restricts the ability to combine and efficiently compare data across databases. In countries where registry-based randomized controlled trials (R-RCTs) are feasible, country-specific definitions of outcomes or disease states that inform patient recruitment can limit the international generalizability of the study findings.[6] Standardized data variables and definitions would provide means to overcome these limitations and enable international R-RCTs and the evaluation of the quality of care according to guideline-recommended quality indicators in multi-country observational cohorts.[7–10]

Currently, there are no contemporary pan-European data standards for cardiovascular disease. The Cardiology Audit and Registration Data Standards (CARDS) was developed in 2004 and was the first European initiative to address this gap in knowledge.[11] The European Unified Registries for Heart Care Evaluation and Randomised Trials (EuroHeart) is an international collaboration initiated and supported by the European Society of Cardiology (ESC) that aims to improve the quality of cardiovascular care through continuous capture of individual patient data.[12] EuroHeart is underpinned by a purpose-built IT platform enabling real-time data recording, monitoring of standards of care, data linkages, and the delivery of R-RCTs and observational studies. During the pilot phase, EuroHeart will focus on four clinical domains, the first of which is the acute coronary syndrome (ACS) and percutaneous coronary intervention (PCI). Here, we describe the development process and the resultant standardized data variables and definitions for ACS and PCI based on the EuroHeart methodology for the development of data standards.[13]

Methods

Working Group composition

A Data Science Group under the auspice of EuroHeart was established in August 2019. This comprised a project chair (C.P.G.), two medical experts (G.B. and S.A.), and a project manager. An international ACS/PCI Working Group was established and included 22 ACS/PCI and registry

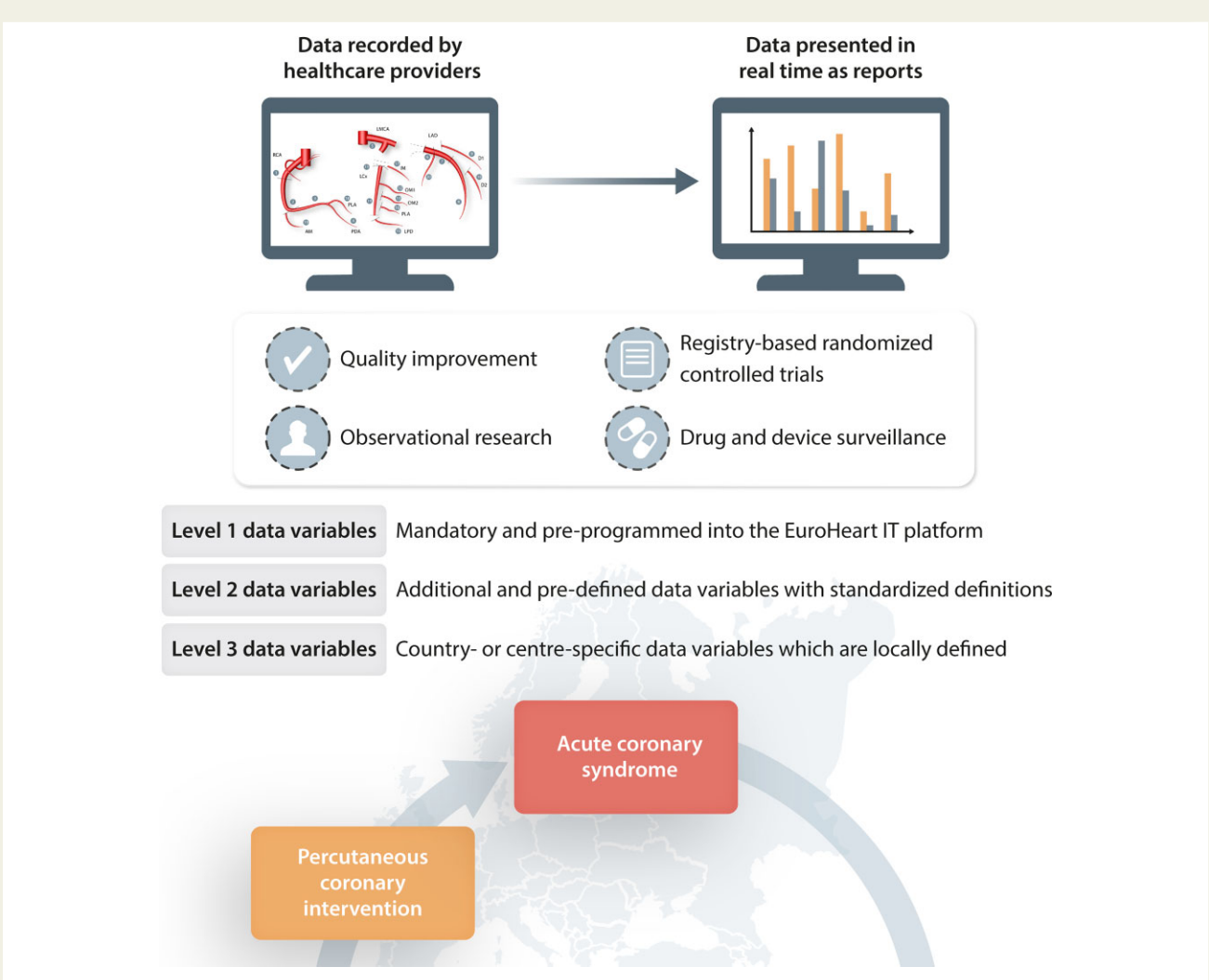

Figure 1 EuroHeart data standards structure.

experts, representing 11 European countries. The selection of the Working Group members was based on ACS and/or PCI expertise and experience of national registries.

Defining data standards

The goal of the development process was to select and define a catalogue of ACS/PCI variables, the extent of which was balanced between all-encompassing and parsimonious. For instance, whereas some registries collect up to 370 variables,[14,15] the Data Science Group opted to limit the number of 'mandatory' variables to between 50 and 100. Three levels of variables were proposed (*Figure 1*). Level 1: 'mandatory' variables that also are pre-programmed into the EuroHeart IT platform and include quality indicators and variables pertinent to accountability and public reporting of quality of care. Level 2: 'additional' variables that are provided together with definitions, but collection not being mandatory and not pre-programmed into the IT platform. Level 3: country- or centre-specific variables that address local regulatory and/or administrative requirements and that are not defined or programmed into the IT platform.

Literature search and evaluation of registries

A systematic review of the published literature (1 January 2004–4 August 2020) identified 554 ACS/PCI variables with accompanying definitions. Evaluation of contemporary national registries in Sweden [Swedish Web-system for Enhancement and Development of Evidence-based care in Heart Disease Evaluated according to Recommended Therapies (SWEDEHEART)], UK [Myocardial Ischaemia National Audit Project (MINAP), National Audit of Percutaneous Coronary Intervention (NAPCI)], and USA [National Cardiovascular Data Registry (NCDR)] was performed.[14–17] Variables defined as quality indicators for ACS were automatically selected as candidate variables.[10] Other variables were assessed according to their evidence base, validity, reliability, feasibility, and applicability. Candidate variables were classified according to the time point of care delivery and, where possible, reconciled with Clinical Practice Guidelines and quality indicators.[7,8,18,19]

Consensus development

The modified Delphi method was used to draw from the candidate variables a final set of ACS/PCI variables. To achieve this, candidate variables were shared with the Working Group, who were asked to assess them for inclusion against the pre-defined criteria and to evaluate the associated definitions. Responses and feedback were evaluated by the Data Science Group and the candidate variable catalogue was updated accordingly. In total, 11 peer-to-peer meetings were held during 2020. The developed variables were thereafter reviewed by the Association for Acute CardioVascular Care (ACVC), European Association of Percutaneous Cardiovascular Interventions (EAPCI), ESC Working Group on Thrombosis, Association of Cardiovascular Nursing and Allied Professions (ACNAP), ESC Patient Forum, and ESC Committee for Young Cardiovascular Professionals.

Results

In total, 302 variables were included in the EuroHeart ACS/PCI catalogue: 152 Level 1 'mandatory' variables (68 for ACS and 84 for PCI) with 20 variables common to both datasets, and 150 Level 2 'additional' variables (*Graphical Abstract*). *Tables 1–7* show the 'mandatory' variables, with condensed definitions. Detailed information about the 'mandatory' variables are provided in Supplementary material online, *Tables S1–S7*, whereas 'additional' variables are provided in Supplementary material online, *Tables S8–S14*.

Table 1 Demographics data variables and definitions

Variable	Registry	Definition and permissible values
Patient identification number	ACS/PCI	Enter the patient's national identification number or a registry generated unique patient identification number
Hospital identification number	ACS/PCI	Enter the hospital's unique identification number
Date of birth	ACS/PCI	Enter the patient's date of birth
Forename	ACS/PCI	Enter the patient's forename
Surname(s)	ACS/PCI	Enter the patient's surname(s)
Sex	ACS/PCI	Enter the patient's sex at birth as either female or male • Female • Male
Postal code	ACS/PCI	Enter the postal code for the patient's current residence

Additional details and complete definitions are available in Supplementary material online, *Table S1*.

Demographics

There are seven 'mandatory' variables in this section, all of which are common between the ACS and PCI data standards (*Table 1*). The section will be replicated in the other EuroHeart clinical domains so that time-independent patient information (e.g. date of birth) may be collected once and applied to all subsequent episodes of care. This section allows the use of permanent unique personal identification numbers to identify patients.[20] When matching the identification number with other data sources, information such as forename, surname, sex, and postal code may be extracted automatically. The EuroHeart IT platform will generate unique patient identifiers for those countries that do not use them, which once assigned may not be changed or reassigned to other patients. Each patient's geolocation is collected as their current residential postal code.

Patient characteristics and comorbidities

The patient characteristics and comorbidities section comprises 13 'mandatory' variables collecting comorbidities relevant to ACS and/or PCI (*Table 2*). The choice of comorbidities was prioritized according to what the Working Group perceived to be information available in an average medical case record. Many of the variables are also relevant when characterizing the patient's risk and are essential when reporting underlying medical history in observational and randomized trials, when understanding trends in quality improvement, and when assessing treatment strategies.

Table 2 Patient characteristics and comorbidities data variables and definitions

Variable	Registry	Definition and permissible values
Height	ACS/PCI	Enter the patient's height on admission (in cm)
Weight	ACS/PCI	Enter the patient's weight on admission (in kg)
Smoking	ACS/PCI	Enter patient's tobacco smoking status • Never smoked • Former smoker • Current smoker • Unknown
Hypertension	ACS/PCI	Enter whether the patient is known to have a diagnosis of hypertension made by a healthcare professional prior to this care encounter • No • Yes • Unknown
Diabetes mellitus	ACS/PCI	Enter whether the patient is known to have a diagnosis of diabetes mellitus made by a healthcare professional prior to this care encounter • No • Diabetes mellitus Type 1 • Diabetes mellitus Type 2 • Diabetes mellitus of other/unspecified type • Unknown
Chronic obstructive pulmonary disease	ACS/PCI	Enter whether the patient is known to have a diagnosis of chronic obstructive pulmonary disease (COPD) made by a healthcare professional prior to this care encounter • No • Yes • Unknown
Moderate or severe chronic kidney disease	ACS/PCI	Enter whether the patient is known to have a moderate or severe chronic kidney disease prior to this care encounter • No • Yes • Unknown
Prior stroke	ACS/PCI	Enter whether the patient is known to have had a stroke prior to this care encounter. More than one option can be selected • No • Ischaemic stroke • Haemorrhagic stroke • Unspecified stroke • Unknown
Prior myocardial infarction	ACS/PCI	Enter whether the patient is known to have had a myocardial infarction prior to this care encounter • No • Yes • Unknown
Heart failure	ACS/PCI	Enter whether the patient is known to have a diagnosis of heart failure made by a healthcare professional prior to this care encounter • No • Yes • Unknown
Atrial fibrillation or atrial flutter	ACS/PCI	Enter whether the patient is known to have a diagnosis of atrial fibrillation (AF) or atrial flutter (AFL) made by a healthcare professional prior to this care encounter • No • Yes • Unknown
Prior percutaneous coronary intervention	ACS/PCI	Enter whether the patient is known to have had a percutaneous coronary intervention (PCI) of any type (not diagnostic angiography) performed prior to this care encounter • No • Yes • Unknown
Prior coronary artery bypass grafting	ACS/PCI	Enter whether the patient is known to have had a coronary artery bypass grafting (CABG) performed prior to this care encounter • No • Yes • Unknown

Additional details and complete definitions are available in Supplementary material online, *Table S2*.

Table 3 Admission data variables and definitions

Variable	Registry	Definition and permissible values
Presenting symptoms	ACS	Enter the patient's symptoms that prompted this presentation. Select the main reason for presentation • Chest pain/discomfort • Dyspnoea • Cardiac arrest • Other • Unknown
Cardiac arrest prior to hospital arrival	ACS	Enter whether the patient had a cardiac arrest prior to hospital arrival • No • Yes • Unknown
Symptom onset, date/time	ACS	Enter the date and time of symptom onset
Arrival method	ACS	Enter the method of current hospital arrival • Self-presenter • Ambulance from home/community • Transportation from another hospital • Already in the hospital • Unknown
First contact with ambulance, date/time	ACS	Enter the date and time of when the ambulance arrived to the patient
Hospital arrival, date/time	ACS	Enter the date and time when the patient arrived in the hospital
Diagnostic ECG, ST/T morphology	ACS	Enter the findings of the diagnostic ECG regarding the ST/T morphology. The first option that best describes the findings should be selected • Normal • ST-segment elevation • ST-segment depression • T-wave inversion • Other • Unknown
Diagnostic ECG, QRS morphology	ACS	Enter the findings of the diagnostic ECG regarding the QRS morphology. The first option that best describes the findings should be selected

Continued

Table 3 *Continued*

Variable	Registry	Definition and permissible values
		• Normal • Ventricular paced rhythm • Left bundle branch block (LBBB) • Right bundle branch block (RBBB) • Pathological Q wave • Other • Unknown
Diagnostic ECG, rhythm	ACS	Enter the findings of the diagnostic ECG regarding the rhythm. The first option that best describes the findings should be selected • Sinus rhythm • Atrial fibrillation or atrial flutter • Ventricular tachycardia • Other • Unknown
ECG establishing need for revascularization, date/time	ACS	Enter the date and time of the first ECG establishing need for coronary revascularization. In cases where imminent revascularization was not indicated, enter the date and time of the first ECG (either before or after hospital arrival)
Heart rate	ACS	Enter the patient's heart rate (in b.p.m.)
Systolic blood pressure	ACS	Enter the patient's systolic blood pressure (in millimetres of mercury)
Killip class	ACS	Enter the patient's Killip class at the time of hospital admission • Killip Class I • Killip Class II • Killip Class III • Killip Class IV • Unknown
Thrombolysis, prehospital	ACS	Enter whether thrombolysis therapy was initiated or administered prior to hospital arrival • No • Yes • Unknown

Additional details and complete definitions are available in Supplementary material online, *Table S3*.

Table 4 In-hospital management data variables and definitions

Variable	Registry	Definition and permissible values
Troponin, elevated	ACS	Enter whether cardiac troponin was elevated during the hospital stay • No • Yes • Unknown
Troponin assay	ACS	Enter the assay used for analysis of cardiac troponin levels • Troponin T • Troponin I • High-sensitivity Troponin T • High-sensitivity Troponin I • Unknown
Haemoglobin	ACS	Enter the first recorded level of haemoglobin during the hospital stay (in g/L)
Creatinine	ACS	Enter the first recorded level of creatinine during the hospital stay (in μmol/L)
LDL cholesterol	ACS	Enter the first recorded level of LDL cholesterol during the hospital stay (in mmol/L). This is not necessarily fasting LDL cholesterol
Left ventricular ejection fraction, assessment method	ACS	Enter the method used to assess left ventricular ejection fraction (LVEF) during hospital stay • Not performed • Echocardiography • Other method • Unknown
Left ventricular ejection fraction	ACS	Enter the left ventricular ejection fraction (LVEF) measured during the hospital stay by echocardiography, angiography, radionuclide, magnetic resonance imaging, or by other methods • ≥50% • 41–49% • 30–40% • <30% • Unknown
Coronary anatomy, assessment method	ACS	Enter the method used to assess the coronary anatomy during the hospital stay • Not performed • Invasive coronary angiography • CT coronary angiography • CT coronary angiography-FFR • Unknown
Anticoagulants, i.v. or s.c.	ACS	Enter whether treatment dose anticoagulant therapy was administered during the hospital stay. This should not include prophylactic low molecular weight heparin (LMWH) or intra-procedural unfractionated heparin (UFH) or intra-procedural bivalirudin • No • Unfractionated heparin • Low molecular weight heparin • Fondaparinux • Bivalirudin • Other • Unknown
Thrombolysis, in-hospital	ACS	Enter whether thrombolysis therapy was initiated or administered during the hospital stay (after hospital arrival) • No • Yes • Unknown
Percutaneous coronary intervention	ACS	Enter whether percutaneous coronary intervention (PCI) was performed during the hospital stay or is planned after discharge • No • Yes, during hospital stay • Yes, planned after discharge • Unknown
Coronary artery bypass grafting	ACS	Enter whether coronary artery bypass grafting (CABG) was performed during the hospital stay or is planned after discharge • No • Yes, during hospital stay • Yes, planned after discharge • Unknown
Reperfusion treatment, date/time	ACS	Enter the date and time of the first reperfusion therapy (thrombolysis, PCI, or CABG) that was administered/performed during the hospital stay

Continued

Table 4 ***Continued***

Continued

Table 4 *Continued*

Variable	Registry	Definition and permissible values
In-hospital events, myocardial re-infarction	ACS	Enter whether the patient had a myocardial re-infarction during the hospital stay • No • Yes • Unknown
In-hospital events, cardiogenic shock	ACS	Enter whether the patient had an episode of cardiogenic shock during the hospital stay • No • Yes • Unknown
In-hospital events, cardiac arrest	ACS	Enter whether the patient had cardiac arrest during the hospital stay • No • Yes • Unknown
In-hospital events, major bleeding	ACS	Enter whether the patient had a major bleeding event during the hospital stay. More than one option can be selected • No • Fatal bleeding • Intracranial haemorrhage • Bleeding requiring surgery • Bleeding requiring transfusion • Other major bleeding • Unknown
In-hospital events, new-onset atrial fibrillation or atrial flutter	ACS	Enter whether a new diagnosis of atrial fibrillation (AF) or atrial flutter (AFL) was made during the hospital stay for patients with no prior history of AF or AFL • No • Yes • Unknown

Additional details and complete definitions are available in Supplementary material online, *Table S4*.

Table 5 Diagnostic coronary angiography data variables and definitions

Variable	Registry	Definition and permissible values
Procedure indication	PCI	Enter the main indication for performing the coronary angiography • Stable coronary syndrome • Unstable angina • NSTEMI • STEMI • Cardiac arrest with STEMI • Cardiac arrest without STEMI • Staged procedure • Rescue PCI • Risk assessment after successful thrombolysis • Valvular heart disease • Arrhythmia • Heart failure/cardiomyopathy • Post-cardiac transplantation • Other • Unknown
Procedure urgency	PCI	Enter the procedure urgency • Elective • Urgent • Emergency • Salvage • Unknown
ECG establishing need for revascularization, date/time	PCI	Enter the date and time of the first ECG establishing need for coronary revascularization
Killip class	PCI	Enter the patient's Killip class at the time of hospital admission or during the hospital stay (prior to the procedure) • Killip Class I • Killip Class II • Killip Class III • Killip Class IV • Unknown
CCS angina grade	PCI	Enter the grade of angina pectoris according to the Canadian Cardiovascular Society (CCS) grading scale • CCS Grade I • CCS Grade II • CCS Grade III • CCS Grade IV • Unknown
Creatinine	PCI	Enter the most recent level of creatinine, but within the last 3 months (in μmol/L)

Continued

Table 5 *Continued*

Variable	Registry	Definition and permissible values
Circulatory support	PCI	Enter whether any circulatory support was used during the hospital stay prior to the procedure. More than one option can be selected • No • Intra-aortic balloon pump (IABP) • Cardiopulmonary bypass • Impella • AutoPulse • Extracorporeal membrane oxygenation (ECMO) • Other • Unknown
Inotropes	PCI	Enter whether inotropic therapy was administered during the hospital stay prior to the procedure • No • Yes • Unknown
Arterial access	PCI	Enter the arterial access(es) punctured/attempted during the procedure. More than one option can be selected • Right radial artery • Left radial artery • Right femoral artery • Left femoral artery • Right ulnar artery • Left ulnar artery • Other • Unknown
Arterial access, date/time	PCI	Enter the date and time when the arterial access for the procedure was accomplished
Segments 1–20	PCI	Enter the per cent estimate (0–29, 30–49, 50–69, 70–89, 90–99, 100%, N/A) of the most severe stenosis in Segments 1–20 as determined by coronary angiography. This does not include collateral circulation. Not applicable (N/A) may be selected when the segment is not visualized
CABG graft, type	PCI	Enter whether a CAGB graft is present and enter the type of the graft • Venous graft • Arterial graft

Continued

Table 5 *Continued*

Variable	Registry	Definition and permissible values
CABG graft, anastomoses segment	PCI	Enter the coronary segment to which the bypass graft is attached • Segment 1 … • Segment 20
CABG graft, lesion finding	PCI	Enter the per cent estimate (0–29, 30–49, 50–69, 70–89, 90–99, 100%, N/A) of the most severe stenosis in the graft selected as determined by coronary angiography. Not applicable (N/A) may be selected when the segment is not visualized
Overall finding in the native coronary arteries	PCI	Automatically generated overall finding in the native coronary arteries based on the responses in Segments 1–20 • Normal/atheroma • 1 vessel disease, not left main coronary artery • 2 vessels, not left main coronary artery • 3 vessels, not left main coronary artery • Left main coronary artery + 1 vessel disease • Left main coronary artery + 2 vessel disease • Left main coronary artery + 3 vessel disease • Isolated left main coronary artery • Inconclusive assessment
Chronic total occlusion	PCI	Enter whether the lesion in the current segment is a chronic total occlusion (CTO) • No • Yes • Unknown
Chronic total occlusion, segment	PCI	Enter the coronary segment in which the lesion is a chronic total occlusion (CTO) • Segment 1 … • Segment 20
Restenosis	PCI	Enter whether the lesion in the current segment is a restenosis • No

Continued

Table 5 *Continued*

Variable	Registry	Definition and permissible values
		• Yes, lesion restenosis • Yes, stent restenosis • Unknown
Restenosis, segment	PCI	Enter the coronary segment in which the lesion is a restenosis • Segment 1 … • Segment 20
Stent thrombosis	PCI	Enter whether the lesion in the current segment is a stent thrombosis • No • Yes • Unknown
Stent thrombosis, segment	PCI	Enter the coronary segment in which the lesion is a stent thrombosis • Segment 1 … • Segment 20
Spontaneous coronary artery dissection	PCI	Enter whether there was a spontaneous coronary artery dissection (SCAD) • No • Yes • Suspected • Unknown
Invasive intracoronary diagnostics	PCI	Enter whether any invasive intracoronary diagnostic assessment was performed before the PCI procedure • No • Yes • Unknown
Invasive intracoronary diagnostics, method	PCI	Enter what invasive intracoronary diagnostics method(s) were performed before the PCI procedure. More than one option can be selected • Not performed • Hyperaemia-based method (e.g. FFR) • Hyperaemia-free method (e.g. iFR, DFR, RFR) • Coronary flow reserve (CFR) • Intravascular ultrasound (IVUS) • Optical coherence tomography (OCT)

Continued

Table 5 *Continued*

Variable	Registry	Definition and permissible values
		• Near-infrared spectroscopy (NIRS) • Other • Unknown
Invasive intracoronary diagnostics, segment	PCI	Enter what segment(s) intracoronary diagnostics was performed before the PCI procedure. More than one option can be selected • Segment 1 … • Segment 20
Invasive intracoronary diagnostics, graft	PCI	Enter whether invasive intracoronary diagnostics was performed in a graft lesion before the PCI procedure • No • Venous graft • Arterial graft
Invasive intracoronary diagnostics, results	PCI	Enter the results of the lowest intracoronary physiology measurement (gradient), the minimal lumen area (mm^2) as measured by intracoronary imaging methods, or maximum lipid core burden index (max $LCBI_{4mm}$) for near-infrared spectroscopy before any treatment interventions
Glycoprotein IIb/IIIa inhibitors	PCI	Enter whether Glycoprotein IIb/IIIa inhibitors was administered during the procedure • No • Abciximab • Eptifibatide • Tirofiban • Unknown

Additional details and complete definitions are available in Supplementary material online, *Table S5*.

Admission

Table 3 depicts the 'mandatory' variables for the admission section. Information about care time points can be difficult to collect but is important given it is used for the derivation of quality indicators.[7,8] Medications at the time of admission form 'additional' variables and are defined in Supplementary material online, *Table S10*.

In-hospital management

This section collects information concerning investigations, treatments, and events occurring in-hospital (*Table 4*). Laboratory results

Table 6 Percutaneous coronary intervention and events data variables and definitions

Variable	Registry	Definition and permissible values
PCI attempted	PCI	Enter whether percutaneous coronary intervention (PCI) was attempted • No • Yes
Passage of wire, date/time	PCI	Enter the date and time when the first guidewire successfully crossed the culprit lesion, not the date when flow was restored
Segment attempted	PCI	Enter the segment attempted during PCI • Segment 1 … • Segment 20
Graft attempted	PCI	Enter whether a graft lesion was attempted during PCI • No • Venous graft • Arterial graft
Type of PCI attempt	PCI	Enter the type of the procedure performed. More than one option can be selected • Plain balloon • Drug-eluting balloon • Stent
Drug-eluting balloon, type	PCI	Enter the drug-eluting balloon that was used in the specific segment. (Device names of drug-eluting balloons used in the specific country)
Drug-eluting balloon, diameter	PCI	Enter the diameter of the drug-eluting balloon. Nominal diameter (in mm) of the drug-eluting balloon that is used should be entered
Stent, type	PCI	Enter the stent that was used in the specific segment. (Device names of stents used in the specific country)
Stent, diameter	PCI	Enter the diameter of the stent. Nominal diameter (in mm) of the stent balloon should be entered
Stent, length	PCI	Enter the length of the stent (in mm)
Adjuvant therapies/equipment	PCI	Enter if any adjuvant therapies were used during the procedure. More than one option can be selected • No • Rotablation • Orbital atherectomy • Lithotripsy • Laser • Thrombectomy • Distal protection device • Other • Unknown
Lesion success	PCI	Enter whether the attempted lesion was successfully treated • No • Yes
TIMI flow, prior to PCI	PCI	Enter the TIMI flow prior to the PCI procedure • TIMI 0 • TIMI I • TIMI II • TIMI III • Unknown
TIMI flow, after PCI	PCI	Enter the TIMI flow after the PCI procedure • TIMI 0 • TIMI I • TIMI II • TIMI III • Unknown
Complete revascularization	PCI	Enter whether a complete revascularization was achieved by the end of the current procedure • No • Yes • Unknown
Additional PCI procedures planned	PCI	Enter whether any additional PCI procedure(s) is planned (either during this hospital stay or after discharge) • No • Yes • Unknown
Peri-procedural events	PCI	Enter whether any events occurred during the procedure. More than one option can be selected • No • Procedure-related myocardial infarction • Vascular access complication • Side branch occlusion

Continued

Table 6 ***Continued***

Continued

Table 6 *Continued*

Variable	Registry	Definition and permissible values
		• Coronary perforation • Coronary dissection persisting at the end of the procedure • Brady-arrhythmia requiring pacing • Arrhythmia requiring DC cardioversion • Cardiogenic shock • Cardiac tamponade • Acute surgical intervention from cath lab • Stroke or transient ischaemic attack (TIA) • Death • Other • Unknown

Additional details and complete definitions are available in Supplementary material online, *Table S6*.

for diagnosis (e.g. cardiac biomarkers), risk stratification (e.g. serum creatinine), and risk factors modification (e.g. low-density lipoprotein cholesterol) are 'mandatory' variables.[7,8,18] Laboratory results for specific situations or subgroups (e.g. N-terminal prohormone of brain natriuretic peptide, C-reactive protein, cholesterol, glucose, and haemoglobin A1c) are 'additional' variables and are detailed in Supplementary material online, *Table S11*. The 2020 ESC guidelines for the management of ACSs in patients presenting without persistent ST-segment elevation recommends the assessment of the left ventricular ejection fraction (LVEF) during the hospital stay, and thus forms a 'mandatory' variable.[7] Categorization of LVEF aligns with the 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure.[21] Given that reperfusion is the cornerstone for the management of patients with ACS, five 'mandatory' variables are dedicated to the evaluation of the coronary artery anatomy and reperfusion strategy.[7,8]

Coronary angiography and percutaneous coronary intervention

This section has two parts. The first part captures information about invasive coronary angiography (ICA) (*Table 5*) and includes an interactive diagram of the coronary tree (*Figure 2*). It provides a solution for the fact that there are international differences in the extent of information recorded in registries (e.g. all ICA procedures in Sweden[14] vs. all PCI procedures in the UK[16]). Equally, the Data Science Group reviewed coronary anatomy visualization tools including the Bypass Angioplasty Revascularisation Investigation (BARI) and the Coronary Artery Surgery Study (CASS) schemes describing coronary anatomy.[22,23] The consensus of the Working Group was to adopt a simplified 20-segment system adapted from the SWEDEHEART registry, which enables interactive reporting of stenoses found in major coronary arteries (*Figure 2*).[14]

Table 7 Discharge management data variables and definitions

Variable	Registry	Definition and permissible values
Hospital discharge, date	ACS	Enter the date when the patient was discharged from the hospital or died during this hospital stay
In-hospital death	ACS	Enter whether the patient died during the hospital stay • No • Yes
Final diagnosis at discharge	ACS	Enter the final diagnosis at discharge • Unstable angina • NSTEMI • STEMI • Other (including no diagnosis of ACS)
Final diagnosis at discharge, ICD-10 code	ACS	Enter the main final diagnosis at discharge according to the International Classification of Diseases (ICD) 10 standard. • I20.0 Unstable angina • I21.0 Acute transmural myocardial infarction of the anterior wall • I21.1 Acute transmural myocardial infarction of the inferior wall • I21.2 Acute transmural myocardial infarction of other sites • I21.3 Acute transmural myocardial infarction of the unspecified site • I21.4 Acute subendocardial myocardial infarction • I21.9 Acute myocardial infarction, unspecified • I22.0 Subsequent myocardial infarction of the anterior wall • I22.1 Subsequent myocardial infarction of the inferior wall • I22.8 Subsequent myocardial infarction of other sites • I22.9 Subsequent myocardial infarction of the unspecified site

Continued

The second part captures information about the procedural indication, urgency, findings, and complications (*Table 6*). It collects information such as date, time, and type of the arterial access, given the use of radial access is recommended as a quality indicator in the

Table 7 *Continued*

Variable	Registry	Definition and permissible values
Aspirin at discharge	ACS	Enter whether the patient was discharged on acetylsalicylic acid (aspirin) • No • Yes • Unknown
$P2Y_{12}$ inhibitors at discharge	ACS	Enter whether the patient was discharged on $P2Y_{12}$ inhibitors • No • Clopidogrel • Prasugrel • Ticagrelor • Other • Unknown
Oral anticoagulants at discharge	ACS	Enter whether the patient was discharged on oral anticoagulants. Vitamin K antagonists include warfarin • No • Vitamin K antagonist • Dabigatran • Rivaroxaban • Apixaban • Edoxaban • Other • Unknown
Beta-blockers at discharge	ACS	Enter whether the patient was discharged on beta-blockers • No • Yes • Unknown
Angiotensin-converting enzyme inhibitors at discharge	ACS	Enter whether the patient was discharged on angiotensin-converting enzyme (ACE) inhibitors. For combination drugs, enter details about both drug classes • No • Yes • Unknown
Angiotensin II receptor blocker at discharge	ACS	Enter whether the patient was discharged on angiotensin II receptor blockers (ARB). For combination drugs (except angiotensin receptor-neprilysin inhibitors), enter details about both drug classes • No • Yes • Unknown

Continued

Table 7 *Continued*

Variable	Registry	Definition and permissible values
Angiotensin receptor-neprilysin inhibitor at discharge	ACS	Enter whether the patient was discharged on angiotensin receptor-neprilysin inhibitor (ARNI) • No • Sacubitril/Valsartan • Unknown
Mineralocorticoid receptor antagonist at discharge	ACS	Enter whether the patient was discharged on mineralocorticoid receptor antagonists (MRA) • No • Spironolactone • Eplerenone • Other • Unknown
Lipid-lowering treatment at discharge	ACS	Enter whether the patient was discharged on lipid-lowering treatment. More than one option can be selected • No • Statins • Ezetimibe • Fibrates • PCSK9 inhibitors • Other • Unknown
Diuretics at discharge	ACS	Enter whether the patient was discharged on diuretics. For combination drugs, enter details about both drug classes. More than one option can be selected • No • Loop diuretics • Thiazide diuretics • Unknown
Sodium-glucose cotransporter-2 inhibitors at discharge	ACS	Enter whether the patient was discharged on sodium-glucose cotransporter-2 (SGLT2) inhibitors. For combination drugs, enter details about both drug classes • No • Yes • Unknown
Oral/subcutaneous antidiabetics at discharge	ACS	Enter whether the patient was discharged on oral or subcutaneous antidiabetic medications. More than one

Continued

Table 7 *Continued*

Variable	Registry	Definition and permissible values
		option can be selected. Sodium-glucose cotransporter-2 inhibitors are entered separately • No • Insulin • Metformin • Glucagon-like peptide-1 (GLP-1) analogue • Dipeptidyl peptidase-4 (DPP-4) inhibitor • Sulfonylurea • Repaglinide • Thiazolidinedione • Alpha-glucosidase inhibitor • Other • Unknown

Additional details and complete definitions are available in Supplementary material online, *Table S7*.

2020 ESC guidelines for the management of ACSs in patients presenting without persistent ST-segment elevation.[7] In addition, thrombolysis in myocardial infarction (TIMI) grades before and following the procedure, and intracoronary equipment and devices used are captured in this section.

Discharge

This section collects information about the final ACS diagnosis and medications prescribed at the time of discharge from the hospital (*Table 7*). The final diagnosis includes ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, and unstable angina [with accompanying World Health Organisations (WHO) standardized International Classification of Diseases (ICD-10) codes]. Medication information includes Anatomical Therapeutic Chemical codes and drug dosages as 'additional' variables (Supplementary material online, *Table S14*).

Discussion

The adoption of harmonized data collections is central for the continuous improvement of cardiovascular care.[24] The lack of internationally recognized data standards has led to large inequalities in monitoring and standards of care within and between European

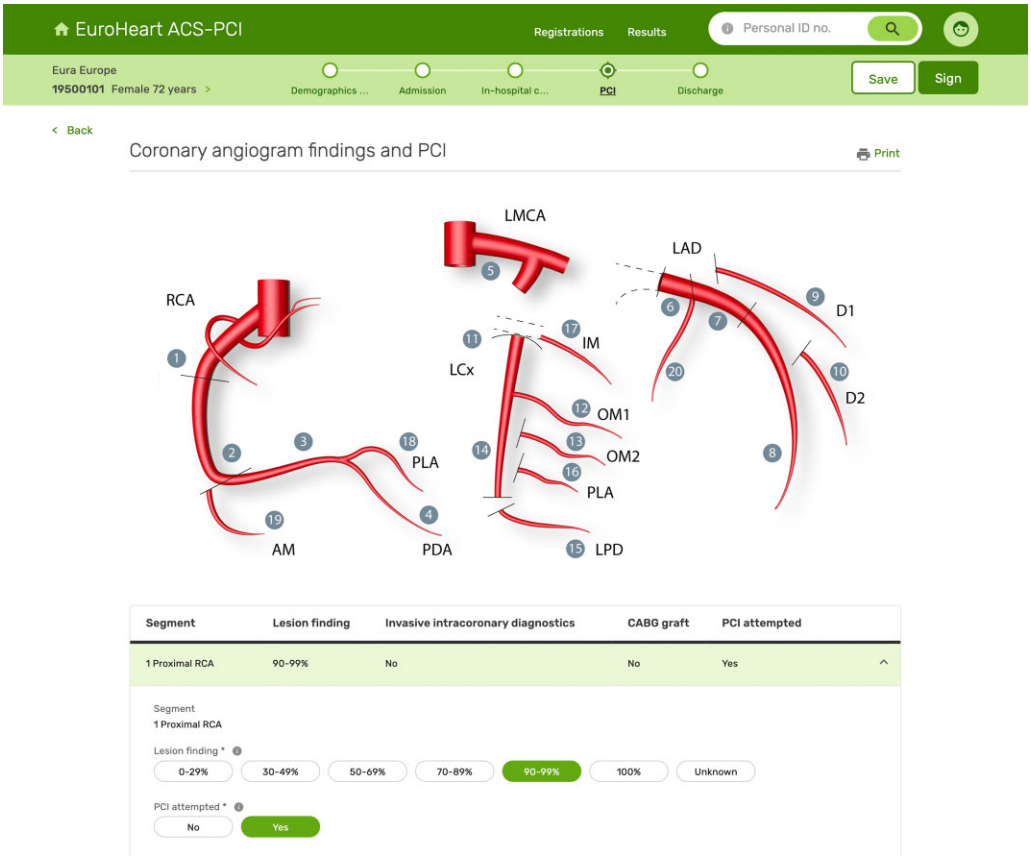

Figure 2 The EuroHeart IT platform and the EuroHeart-percutaneous coronary intervention coronary artery segments.

countries and also resulted in expensive and inefficiently coordinated and delivered studies of cardiovascular treatments.[25] Currently, there are no contemporary pan-European data standards for ACS and PCI. The EuroHeart project of the ESC, by means of a structured methodology, has defined a catalogue of data standards for ACS and PCI, which will be implemented into a bespoke IT platform to facilitate harmonized country-level quality improvement, international observational and registry-based randomized research, and post-marketing surveillance of devices and pharmacotherapies.

The existing European national cardiovascular registries comprise distinct and discordant entities with differing data variables and definitions.[26] This substantially limits their usability in collaborative large-scale studies. Data standards and case report forms presented by CARDS, the EURObservational Research Programme (EORP), and the American College of Cardiology (ACC) and the American Heart Association (AHA) have been used in national registries and in clinical trials,[11,27,28] but differ in their data variables and definitions. Furthermore, no previous international cardiovascular data standards initiative has provided the means by which data may be efficiently collected in 'real-world' settings. Moreover, the ACC/AHA data standards for coronary artery disease and PCI contain over 300 variables that make it difficult to implement in a pragmatic registry.[28,29] In contrast, the EuroHeart data standards presented in this article have a restricted number of mandatory ACS/PCI variables, bolted onto an IT platform for effective data collection.

After years of steady decline, the reduction of mortality rates post-myocardial infarction has plateaued in many countries; cardiovascular disease remains the main cause of death worldwide and its burden is increasing in low- to middle-income economies.[30] The standardized collection of cardiovascular data and the understanding of how to use observational and randomized data in cardiovascular medicine is a clear unmet need and an important next step towards defining variation in cardiovascular care and facilitating continuous quality improvement.[4] The emergence of new devices and drugs for the management of cardiovascular disease provides opportunities for improved outcomes but requires post-marketing surveillance. In addition, the growing complexity and financial burden of traditional randomized controlled trials create a need to develop innovative ways to conduct high-quality, yet cost-effective research. National registries which implement uniform data standards will facilitate rapid and efficient post-marketing surveillance of device therapies and pragmatic R-RCT with pooled data from multiple geographical locations.[6]

Since 2021, the EuroHeart IT platform collects all 'mandatory' variables and supports the development of 'additional' variables in participating countries. Furthermore, the EuroHeart IT infrastructure includes applications for clinical reporting in the local healthcare system and provides tools for observational research, R-RCTs, and post-marketing surveillance of drugs and devices. Patient data are collected continuously in the healthcare system on a country level, and the national or regional registry centres are responsible for the storage and data protection according to the existing legal framework. Signed informed consent will not be required for data collection for quality development in most countries. For planned reports presenting the standards of care in different countries participating in EuroHeart, only deidentified and aggregated data will be shared by the participating registries/countries. Thus, for the collaboration on the development of quality of care, no individual patient-level data will be transferred outside the local country/region. However, for prospective research projects, such as R-RCTs or drug and device monitoring, informed consent from participants' will be required as for any clinical trial. In these cases, selected anonymized individual study data may be transferred for analysis to a central repository according to clinical trial protocols. Finally, as part of mutually agreed international epidemiological research projects and based on ethical and regulatory approval, anonymized retrospective registry cohorts may be transferred to a central repository for pre-defined statistical analysis. In all cases, the national/regional registry parties are responsible for defining the legal framework applicable to their participation in EuroHeart and its various features, and for ensuring that they do not violate either local or international law.

We recognize the limitations of the EuroHeart data standards development process. This includes the use of expert opinion (which may be biased) for the selection of the final data variables and definitions from those identified in the literature review. However, the EuroHeart ACS and PCI data standards were developed using a structured and recognized methodology for selecting the expert panel and for obtaining their opining and feedback. Likewise, the inclusiveness of the Working Group, which comprised experts from many European countries, provided a robustness and transparent framework for the development of the variables and definitions. Despite the data standards being reviewed by the ESC Patient Forum, future Working Groups may benefit from the inclusion of patients and wider members of the multidisciplinary team for ACS and PCI such as nurses and pharmacists. Of note, the data standards proposed in this document are based on the evidence available at the time of development. Accordingly, updates may be required as more and new knowledge becomes available.

Conclusions

This document presents the first set of data standards, developed as part of the EuroHeart project, which aims to harmonize data variables and definitions across common cardiovascular domains. In total, 68 and 84 'mandatory' variables for ACS and PCI domains have been proposed, respectively. Also, several 'additional' variables have been defined. Once fully adopted into the EuroHeart IT platform, the data standards will facilitate country-level quality improvement, observational and registry-based randomized research, and post-marketing surveillance of new devices and pharmacotherapies.

Supplementary material

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

Acknowledgements

We thank the members of the ACS/PCI Working Group for their expertise when developing the ACS and PCI data standards; Joakim Alfredsson (Sweden), Branko Beleslin (Serbia), Mark de Belder (UK), Ana Djordjevic-Dikic (Serbia), Jorge Ferreira (Portugal), Sudhakar George (UK), Claes Held (Sweden), Alar Irs (Estonia), András Jánosi (Hungary), Zumreta Kušljugić (Bosnia and

Herzegovina), Sílvia Monteiro (Portugal), Belma Pojskić (Bosnia and Herzegovina), Svein Rotevatn (Norway), Andrea Rubboli (Italy), Rui Teles (Portugal), José María de la Torre Hernández (Spain), Cristian Udroiu (Romania), Clive Weston (UK), and Troels Yndigegn (Sweden). We also thank Adrian Banning (UK), Scot Garg (UK), David Hildick-Smith (UK), Tim Kinnaird (UK), and Rod Stables (UK) for their support and expertise during the development of the ACS and PCI data standards. We thank Catherine Reynolds (EuroHeart Project Manager, Leeds Institute of Cardiovascular & Metabolic Medicine, University of Leeds, Leeds, UK), Ebba Bergman and Lan Vu Thi (EuroHeart Project Managers, Uppsala Clinical Research Center, Uppsala, Sweden) for their support and contribution to the EuroHeart project. We thank Ida Björkgren (Uppsala Clinical Research Center, Uppsala, Sweden) for the editorial support.

Funding

This work was supported by the European Society of Cardiology.

Conflict of interest: G.B. has nothing to declare with respect to this manuscript. Outside this work, G.B. has received lecture/speaker fees from AstraZeneca and Boehringer Ingelheim; expert committee fees from Novo Nordisk. S.A. and P.L. have nothing to declare. L.W. has nothing to declare with respect to this manuscript. Outside this work, L.W. reports institutional research grants from AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb/Pfizer, GlaxoSmithKline, Merck&Co, and Roche Diagnostics; consulting fees from Abbott. A.P.M. has nothing to declare with respect to this manuscript. Outside this work, A.P.M. received personal fees for participation in committees of studies sponsored by Astra Zeneca, Bayer, Fresenius, Novartis. D.E. has nothing to declare with respect to this manuscript. Outside this work, D.E. reports speaker and advisory board fees from AstraZeneca, Sanofi, Bayer, Boehringer Ingelheim, and Chiesi. B.C. has nothing to declare with respect to this manuscript. Outside this work, B.C. has received in kind support from Roche Diagnostics and iRhythm for clinical studies of atrial fibrillation. C.P.G. has nothing to declare with respect to this manuscript. Outside this work, C.P.G. has received grants from Abbott and BMS; honoraria for lectures and scientific advice from Amgen and AstraZeneca.

Appendix

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In collaboration with: The Association of Cardiovascular Nursing and Allied Professions (ACNAP), Association for Acute CardioVascular Care (ACVC), European Association of Percutaneous Cardiovascular Interventions (EAPCI), EURObservational Research Programme (EORP), ESC Patient Forum, ESC Working Group on Thrombosis, and the ESC Committee for Young Cardiovascular Professionals have endorsed and were involved in the review of the EuroHeart ACS/PCI data standards.

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Corrigendum

https://doi.org/10.1093/eurheartj/ehac187
Online publish-ahead-of-print 8 April 2022

Corrigendum to: $P2Y_{12}$ inhibitor adherence trajectories in patients with acute coronary syndrome undergoing percutaneous coronary intervention: prognostic implications

European Heart Journal, https://doi.org/10.1093/eurheartj/ehac116.

In the originally published version of this manuscript, the graphical abstract had two errors, as follows: (1) The legend incorrectly labeled Group 5 as "persistent nonadherence"; the correct label for this group is "persistent adherence". (2) the rightmost graphical abstract figure was a duplicate of the middle figure; it has been replaced with the correct figure, a Kaplan-Meier plot of major adverse cardiovascular events by $P2Y_{12}$ inhibitor adherence trajectory group, stratified by stent type. These errors have been corrected.