ESC
European Society of Cardiology

EuroHeart

Pilot Country Evaluation Form A: Countries Developing New National/Regional Quality Registries on the Common EuroHeart Registry IT-Platform

Please note that you can refer to previous responses to avoid duplication.

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No	Question	Response
General information – National setting		
1.	Are there any existing national/regional cardiovascular health registries? Please specify if they are indications/procedure-specific i.e. ACS, PCI, AFib or other.	There are no specific nosological cardiovascular registries in Lithuania. Data on morbidity and mortality are extracted from the administrative database of the State Health Insurance Fund. These data are analyzed per request for audit of Myocardial Infarction cluster and specialized Heart Failure care.
2.	What is the purpose of these health registries? ☒ Administrative ☒ Reimbursement ☒ Drug monitoring ☐ Device monitoring ☒ Improving quality of care ☐ Other	National digital health platform ensures storage and exchange of EHR, ePrescription and medical images, referrals, discharge letters, visit descriptions, birth and death certificates. National digital health service covers 100% of insured patients, 100% pharmacies and almost 100% healthcare institutions. 99% of reimbursement prescriptions are electronic. 70% of inpatient epicrisis, 90% of outpatient visit descriptions, 99% of referrals, 100% of births and death certificates are electronic. Data on hospitalizations, in-hospital and out-of-hospital mortality, some coded procedures (like ICD implantations) are used as quality care indicators.

3.	What is the percentage of participation at a patient level (patients per hospital, patients per region/country) and hospital level (hospital per region/country) in these health registries? Is registration mandatory?	National digital health platform ESPBI is mandatory, it was launched in 2016. It covers 100% of insured patients, 100% pharmacies and almost 100% healthcare institutions. 70% of inpatient epicrisis, 90% of outpatient visit descriptions, 99% of referrals, 100% of births and death certificates are electronic.
4.	Describe how these registries are used in clinical practice. Include information on how, by whom and when data is registered.	The ESPBI platform contains text files, which are filled in by physicians and nurses. They represent standardized discharge letters, visit descriptions and forms for reimbursement approved by the Ministry of Health.
5.	Are there unique national personal identifiers?	Subject personal ID and insured identification code are used.
6.	Are there electronic health records (eHR)? Describe the use of eHRs at the hospital, regional and country level.	70% of inpatient epicrisis, 90% of outpatient visit descriptions, 99% of referrals, 100% of births and death certificates are electronic placed in the national digital health platform ESPBI, which is synchronized with HIS.
7.	Are there national/local health registries in other disease areas?	Tuberculosis registry is established in 1995, and Cancer registry exists since 2016.
8.	Provide information on the number of hospitals admitting cardiac patients, hospitals with catherisations labs, as well as the yearly number of patients with PCI procedures and patients with ACS on a national/regional basis?	Cardiac patients are admitted in approximately 40 hospitals, catheterization labs are in 5 big hospitals which comprise Myocardial Infarction Cluster. Roughly 7,400 PCI procedures are performed yearly. In 2019 according to National health insurance fund, 7,300 myocardial infarctions are diagnosed in 5 cluster hospitals, and total 9,900 cases are registered in the country.
9.	What proportion of the health care for patients with ACS-PCI is public or private? How might this influence the establishment of a quality registry?	All 5 Myocardial Infarction Cluster centers are public, with a Ministry of Health as a founder, therefore potentially homogenous environment of the registry may be expected.

Development of new national/regional quality registries The national/regional quality registries that will be developed in the EuroHeart pilot phase might be implemented in an entire country our in selected region(s) of a larger country. The following questions aim to provide an understanding of the planned national/regional ACS-PCI quality registry. Therefore are the responses to Questions 10-21 specific for the planned ACS-PCI quality registry, as oppose to questions 1-9 which refers to the country in general.		
10.	What are the organisational plans for the national/regional quality registry? **Consider:** - **Governance** Composition of the steering committee, process of appointing steering committee members and the required competences. - **Management/Support personnel** Project managers, data managers, statisticians etc. - **Technical management** Note separate questions 22-23. - **Key stakeholders** Please include names if there are already national champions and/or leading groups identified.	It is planned that National ACS-PCI quality registry would involve 5 Myocardial Infarction Cluster centers in 5 biggest cities: Vilnius, Kaunas, Klaipėda, Šiauliai, Panevėžys. Steering committee is expected to include Vice-minister of Health, Ministry representatives of the Department of Digital Health, Board members of the Lithuanian Society of Cardiology (Jelena Čelutkienė, Olivija Gustienė, Giedrius Davidavičius), Administration representatives and IT specialists of the 5 Myocardial Infarction Cluster centers. Ministry of Health is supposed to appoint and regularly renew steering committee members, as well as designate project and data managers. Lithuanian Society of Cardiology could contribute by providing statistician or other support of the registry. Key stakeholders: Ministry of Health, Lithuanian Society of Cardiology, Myocardial Infarction Cluster centers.
11.	Who will be the owner of the registry?	Ministry of Health
12.	Who will control the registry data?	Ministry of Health
13.	Does data registration for the purpose of quality development require that patients sign an informed consent?	This question requires clarification with State Data Protection Inspectorate.
14.	What would be the anticipated participation in the registry at a patient level (patients per hospital, patients per region/country) and hospital level (hospital per region/country)? Would participation in the registration be voluntary or mandatory?	The purpose is to include 100% of ACS patients because Ministry of Health ordered to evaluate quality care indicators in the treatment of myocardial infarction with and without ST segment elevation. This ensures mandatory participation of the Myocardial Infarction Cluster centers.

15.	Provide a description of the hospitals/centers anticipated to be included in the registry (if different from the response to question 8). Include the number of hospitals/centers, catherisations labs, yearly PCI interventions and eligible patients. Include also information on current or previous collaborations and if there are any existing infrastructures facilitating collaborations between the hospitals/centers.	5 Myocardial Infarction Cluster centers with 24/7 service in the 5 biggest cities: Vilnius, Kaunas, Klaipėda, Šiauliai, Panevėžys – are anticipated to be included in the registry. Ministry of Health is a founder of these tertial care hospitals. Roughly 7,400 PCI procedures (both in acute and chronic settings) are performed yearly. In 2019 according to National health insurance fund, 7,300 myocardial infarctions are diagnosed in 5 cluster hospitals. The service of these centers is coordinated by the Cluster Committee and is regularly analyzed.
16.	Is there a willingness of hospitals/centers to participate in a quality registry? Also consider if there are challenges/reluctance to participate. Is there already an ongoing communication with these hospitals/centers regarding starting a quality registry and to collaborate with EuroHeart?	All 5 Myocardial Infarction Cluster hospitals are represented in the Board of the Lithuanian Society of Cardiology, which initiates the participation of Lithuania in the registry. These regional representatives have already involved the administration and IT specialists of cluster hospitals in the first EuroHeart project meeting. The idea is to integrate dedicated registry forms into local HIS and ESPBI in order to avoid additional workload for HCPs.
17.	What measures can be taken to ensure continuous registration and high data quality?	The idea is to integrate dedicated registry forms into local HIS and national ESPBI platform trying to avoid additional workload for HCPs. This would ensure prospective data collection and continuous registration.
18.	Describe how the registry would be integrated with current clinical practice. Include information on how, by whom and when data would be recorded.	The same electronic records should include registry data set and serve as visit descriptions and discharge letters, because HCPs are reluctant to fill in quality variables twice. Physicians and nurses are supposed to enter registry forms. The aim is to create dedicated subsystem in the ESPBI platform.
19.	Is there support from the National Cardiac Society for developing national quality registries and collaborating with EuroHeart?	The Lithuanian Society of Cardiology is very enthusiastic about the EuroHeart project, considering the urgent need of treatment quality analysis and improvement, especially in ACS-PCI and HF areas.
20.	Is there support from the national and/or local health authorities/government (e.g. Department of Health) for developing national quality registries and collaborating with EuroHeart?	Last ministerial decrees confirmed the set of quality care indicators in the field of myocardial infarction and heart failure, and it becomes clear that collection of such kind of data is impossible without registries. Vice-minister of Health dr. Kristina Garuolienė and Department of Digital Health are very positive about collaborating with EuroHeart project.
21.	How would the development and maintenance of the registry be funded? Consider both: 1) **Short-term funding**	The attempts to allocate short- and long-term funding will be made seeking for investments funds when planning next year and future healthcare

	2) **Long-term funding**	budget. The Lithuanian Society of Cardiology will look for private sponsorship for specific tasks, such as statistical analysis.
Technical registry management The national/regional registries will be developed on the common EuroHeart Registry IT-platform. If selected as a pilot country the platform will be licensed to the country/region at an annual fee of 40 000 Euro. The country/region might also request additional consultancy hours for support with implementation, development etc. that will be regulated in separate contracts. The license offers a toolbox for developing cardiovascular quality registries. To develop and implement quality registries each country/region will need to set-up their own technical development and support organisation.		
22.	Describe the plan for organising the technical management of the registry? **Note:** Include information if there is an existing technical support organisation or if the plan is to set-up an new organisation. If the plan is to outsource the technical management to a private company, please provide name, description and collaborative history if any.	The project and data managers, IT specialists would be the part of Department of Digital Health of the State Health Insurance Fund (Ministry of Health).
23.	The general estimation is that the technical registry management organisation will require 3-5 full-time employees to develop and implement the registry on the EuroHeart Registry IT-platform. Recruitment of personnel might sometimes be challenging. Please estimate the level of difficulty to allocate the below listed resources/capabilities: **1=Easy 2=Doable 3=Hard 4=Impossible** **Q1.** Experienced in developing and maintaining IT-based registers 1☐ 2 ☐ 3 ☒ 4 ☐ **Q2.** Experienced in data or information management 1☐ 2 ☐ 3 ☒ 4 ☐ **Q3.** Experienced in statistical data report systems (SAS or similar) 1☐ 2 ☐ 3 ☒ 4 ☐ **Q4.** Experienced in data output 1☐ 2 ☒ 3 ☐ 4 ☐ **Q5.** Experienced in Java development	*Additional comments if needed:*

	1☐ 2 ☐ 3 ☒ 4 ☐ **1=Easy 2=Doable 3=Hard 4=Impossible** **Q6.** Competence and experience in registry development 1☐ 2 ☐ 3 ☒ 4 ☐ **Q7.** Long-term commitment and competence for technical upgrades 1☐ 2 ☐ 3 ☒ 4 ☐ **Q8.** Long-term commitment and competence for maintaining and supporting the registry organisation. 1☐ 2 ☐ 3 ☒ 4 ☐	
Post-registration follow-up in complementary registries or other means of individual follow-up		
24.	Is there a national, regional and/or hospital registration on vital status and cause of death?	The State Register of Death Cases and Their Causes was established in 2010. It collects, accumulates, systematizes, stores and provides data to legal entities (http://www.hi.lt/en/mortality-in-lithuania.html).
25.	If there is a cause of death registry, clarify the completeness of data registration (per international classification of disease (ICD) code or other). Include a description of the quality of data and measures taken to ensure data quality.	There are methodical recommendations confirmed for the filling in a death certificate. It includes place and type of death (for example, accident, disease or sudden death, circumstances, direct and intermediate causes of death, primary diagnosis of causal disease, other important comorbidities related to death, association with surgery, ICD codes, the type of specialist who completed a certificate).
26.	Are there other national/regional registries that might cover subsequent clinical events and are based on a national unique personal identifier? Examples of registries: - Hospital admission diagnoses (ICD-code) - Interventional procedures (ICD-code) - Out-patient diagnosis/visits (ICD-code) - Other registries (other diagnosis) Please include information about the data quality of these registries and other limitations.	The information system “Sveidra” is one of the main activity systems of the State Health Insurance Fund, which helps to manage the accounting of medical services paid for from the Compulsory Health Insurance Fund and to control the provision of services. All state medical institutions, pharmacies, medical and health care institutions that have concluded agreements with the Insurance fund provide data to and receive data from Sveidra, as well as Sveidra is one of the main sources of data provision to E-health system. It includes hospital admission diagnoses, out-patients diagnoses based on ICD codes, medical services and interventional procedures based on ACHI codes. DRG system is used for coding.

27.	Will it be possible, from a legal and feasible perspective, to merge data from other national registries and data sources with a national/regional quality registries (based on national unique personal identifier) to gain information on outcomes? Please consider if there are any legislation aspects affecting data merging on a patient-level and group-level. Also include information if there are possibilities and challenges with aggregated data analysis and measures to overcome these challenges.	We have already experience of merging data from "Sveidra" database with data from the State Register of Death Cases and Their Causes or clinical databases accumulated in the research projects. National unique personal identifiers (personal ID) are used for the merging before data are anonymized. We obtained the approval of the Biomedical Ethics committee for the data merging, and in this way complete mortality and rehospitalizations data are derived. Specific approvals are not required for the group-level or aggregated data analysis.

International collaboration on data

A. Quality development

The national/regional EuroHeart dataset is owned by the national/regional registries. Collaborative analyses on the EuroHeart dataset will be planned by the EuroHeart Foundation. Identical statistical analyses will be made by the participating countries/regions followed by a transfer of aggregated group results to the EuroHeart Data Science Center for further analyses. Thus, the current plan is that only aggregated data, no individual data, will be shared with the EuroHeart Data Science Center.

B. Registry-based randomised clinical trials (R-RCT) and safety surveillance of new drugs and devices

Registry-based randomised clinical trials (R-RCT) and drug/device surveillance projects will be performed based on patients signed informed consent and the individual data will be locally anonymised and stored in a separate database. The database will be regularly transferred to the EuroHeart Data Science Center same as for a traditional RCT.

28.	**Regarding A. Quality development** Do you foresee any issues with collaborations that share **aggregated data for quality development analyses** in the countries participating in Euroheart? If yes, please describe the potential issues in detail.	No
29.	**Regarding B. R-RCTs and new drug/device surveillance projects** Do you foresee any issues with sharing **anonymised individual data based on patient informed consent** for participation in R-RCTs and drug/device surveillance projects? If yes, please describe the potential issues in detail.	No

Please add any additional comments: