EURopean HOspital Benchmarking by Outcomes in acute coronary syndrome Processes

The EURHOBOP Project
Executive Agency for Health and Consumers
Agreement number 2008 13 12

Deliverable N. 2

Title:

Protocols and Data Collection Forms Preparation

February 4th, 2010
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The EURHOBOB Project

Main beneficiary

Institut Municipal d’Assistència Sanitària - Institut Municipal d’Investigació Mèdica (IMAS-IMIM), Spain
Municipal Institute of Health Assistance - Municipal Institute of Medical Research

Associated beneficiaries

Ελληνική Καρδιολογική Εταιρεία (HCS), Greece
Hellenic Cardiologic Society

Dipartimento di Epidemiologia ASL Roma E (DEASL), Italy
Department of Epidemiology, Health Authority Roma E

Faculdade de Medicina da Universidade do Porto (FMUP), Portugal
University of Porto Medical School

Helmholtz Zentrum München - Deutsches Forschungszentrum für Gesundheit und Umwelt (HMGU), Germany
Helmholtz Center Munich - German Research Center for Environmental Health

Terveyden ja hyvinvoinnin laitos (THL), Finland
National Institute for Health and Welfare

Association pour l’étude et la prévention des maladies dégénératives du système cardio-vasculaire - "Projet MONICA" (AEPMCV), France
Research and Prevention on Cardiovascular Diseases – The Toulouse MONICA Project

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National Institute of Health in Italy

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Work package 1: Coordination of the project

WP leader: Jaume Marrugat IMAS-IMIM

Project Management

This work-package includes all the tasks and actions necessary to coordinate the ensemble of tasks involved in the project-component work-packages, adhering to the agenda described on the technical Addendum I. These tasks include but may not be limited to:

Communications with HEPAP: in telephone, email, WEBEX or physical meetings or conferences as necessary by the development of the project.

Communications with partners: in telephone, email, WEBEX or physical meetings or conferences as necessary by the development of the project.

Submission of deliverables to the on due course as determined in Technical Addendum I.

Organisation of kick-off meeting, 3 workshops and a final conference.

A final version of the software to be created for dissemination purposes will be created.

Coordination of the preparation of the leaflet for the participants and a brochure focus on the results achieved during the project, which will be prepared by the participants and translated in all the languages spoken in the participant countries using their own internal resources.

GENERAL PROJECT MEETINGS: Overview of the different meetings planned in the lifecycle of the project

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Venue</th>
<th>Participants</th>
<th>Organized by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kick-off meeting</td>
<td>BARCELONA</td>
<td>All partners, EU officer</td>
<td>MAIN PARTNER: IMAS-IMIM</td>
</tr>
<tr>
<td>2nd annual meeting</td>
<td>ATHENS</td>
<td>All partners, EU officer</td>
<td>Partner HCS-ATTIKON</td>
</tr>
<tr>
<td>3rd annual meeting</td>
<td>PORTO</td>
<td>All partners, EU officer</td>
<td>Partner FMUP</td>
</tr>
<tr>
<td>Final Conference</td>
<td>BARCELONA</td>
<td>All partners, EU officer</td>
<td>MAIN PARTNER: IMAS-IMIM</td>
</tr>
</tbody>
</table>

ONSITE VISIT TO PARTNERS: Main partner on-site visits to the associated partners. The Coordinator has planned on site individual visits to each partner to follow the local development of the data collection. Main partner on-site visits to the associated
partners. The Coordinator has planned on-site individual visits to each partner to follow the local development of the data collection.

**EXTERNAL SCIENTIFIC ADVISOR BOARD MEETING (ESAB):** We will appoint an independent External Scientific Advisor Board with a mix of three selected Public Health authorities, clinician, researchers and epidemiologists who will examine the results at mid period of EURHOBOP completion. The representative of DG SANCO will also be invited to the Committee.

**NURSES/MEDICAL RECORD EXTRACTORS TRAINING MEETING:** Medical record extractors will be trained and certified in Barcelona. This will include a one-night and one and a half day stay for two extractors, that will be covered by each centre funds (requested in the budget). The coordinating centre will hire expert medical record extractors who will take care of the training and candidate certification with a number of record extraction done during the process.
Work package 2: Dissemination of the results - Protocol

WP leader: Marina Torre ISS

Dissemination is a key action in a project to make available and spread the achieved results to a public as wide as possible, and to share them with all the stakeholders. Most of the dissemination activities will be therefore related to making the results of the project available both as scientific and informative publications for policy makers, stakeholders and citizens.

The aim of this WP is to define the diffusion policy and to carry out the dissemination of the results. Diffusion policy will be a result of an agreement among partners in accordance to legal and ethical provisions. The EURHOBOP dissemination strategy will be thoroughly described in the dissemination plan. The main activities that will be carried out in WP 2 will consist of:

- designing a logo to identify the project
- preparing the dissemination plan
- conducting the necessary activities to bridge EUPHORIC vs EURHOBOP and designing a website in cooperation with the selected technological partner
- designing and editing the information leaflets
- identifying the stakeholders that will receive the final products of the project
- cooperating with the Project coordinator in the preparation of a final brochure
- assisting the Project coordinator in promoting through the website the project final conference

Moreover WP2 will be also responsible of the preparation of a set of standardised tools to be used when disseminating the project results (Technical report /Deliverables coversheet; Slide scheme to be used in Congresses/conferences presentations).

Designing a logo to identify the project

To characterize the project while disseminating the results, in cooperation with the technological partner selected to implement the website, a logo will be designed to be used in all of the publications related to EURHOBOP (website, publications, reports, presentations, etc). The logo will be officially adopted after approval by all the partners during the kick-off meeting.
Preparing the dissemination plan

To carry out the dissemination, a detailed dissemination plan will be defined. It will include the description of the dissemination policy, of the tools used for the dissemination (mainly the website) and of all the proposals submitted by the associated beneficiaries and collaborating partners about the dissemination of the EURHOBOP results in their own networks (public health, scientific societies, universities) also taking into consideration the collection of feedback (comments, suggestions) that will come from the addressees.

Besides the activities related to the implementation of the website, the dissemination activities carried out by all the partners will include the preparation of a final brochure (see below), the participation in conferences and the publication of specific scientific papers.

Conducting the necessary activities to bridge EUPHORIC to EURHOBOP and designing a website in cooperation with the selected technological partner

The main tool supporting the dissemination of the results will be the project website (www.eurhobop.eu).

EURHOBOP is based on the preliminary results obtained in the EUPHORIC (www.euphoric-project.eu) cardiovascular pilot study. During EUPHORIC, the beta-version of a set of mathematical functions useful to benchmark hospitals in terms of their in-hospital mortality for acute coronary syndrome patients were developed and uploaded into the members’ area of the project website. The EUPHORIC project website was developed by the Inter-University Consortium for the Application of Super-Computing for Universities and Research (CASPUR www.caspur.it) that provided a high professional contribution in the management of this task. Therefore, in order to benefit of the gathered previous experience, CASPUR is in charge, as technological partner, of continuing and improving the set up of the EURHOBOP website. In close cooperation with CASPUR, as stated in the Annex 1 to the EURHOBOP Grant Agreement and in the EUPHORIC final report, the WP2 leader will also manage the bridging between EUPHORIC and EURHOBOP. Therefore CASPUR’s role in the EURHOBOP project will be to provide technical support for both the design and the implementation of the website together with the deployment and the housing of the site itself.

The EURHOBOP website will be both an output of the project and the means by which most of the results will be disseminated to the international audience. It will be housed at CASPUR and will be reachable at www.eurhobop.eu. The website will be publicized by the partnership organizations and links to the EURHOBOP website will be made available from other appropriate places. The website will be user-friendly, periodically
updated, linked to the EU official website and accessible through the EU official web site in order to make the results available to EU authorities, institutions, study participants and citizens. Moreover, it will be achieved by following the W3C accessibility guidelines and the usability rules.

A password protected access to the website (members area) will enable only the EURHOBOP registered partners (Main and associated beneficiaries and collaborating partners) to contribute to the development of the project and enter the relevant information while, on the other hand, public access to the web will guarantee the dissemination of the information to both the scientific audience and the public. Therefore the website will be organised in order to support the project in two main activities:

1) **The validation of the mathematical function developed under EUPHORIC by a selected list of participating hospitals**

A specific section will be dedicated to this issue in order to allow the participating hospitals and those enrolled by partner HOPE to input their data after a registration step. The website will also host, in the members area, the beta version of the benchmarking algorithm that will be validated during the project in cooperation with all the participating hospitals. This beta version will be accessible upon registration of the hospitals invited by the project partners. A disclaimer, previously developed by subcontracted attorney services and approved by the Main Beneficiary before being uploaded onto the website, will appear to the registered user of the benchmarking algorithm requiring acceptance and understanding of the limitations and user conditions of the functions.

The access to the functions will be enabled in two ways:

1) by manually entering on the web site the requested hospital aggregated data,

2) in a batch mode that will allow a registered user to upload on the web site a file with a pre-specified structure with anonymous individual patient data.

In the second case the files will be forwarded to the IMIM web site to be processed by the IMIM working group that will send back the results of the analysis directly to the Hospital that originated them (without using EURHOBOP website link).

2) **The dissemination of the results**

On the website *ad hoc* designed information will be provided to the EU competent authorities, national institutions in the field of health, study participants and EU citizens. A description of the project and of the participating partners as well as a brief overview of the national context of the participating countries with regard to their health systems, to the information on the data sources and protocols available to measure outcomes in Acute Coronary Syndrome will be provided. From the website it will be also possible to download technical documents. As well, a list of useful contacts (links to institutions,
associations, scientific societies, organizations operating in the health field) will be available. The website will foresee the possibility to host specific pages with contributions from each WP.

Selected documents will be available in English to make health information as accessible as possible to the users. All the disseminated documentation, information or material will be free of charge and accessible by internet.

Dissemination activities have great importance especially in the months after the end of the project. In order to allow the more complete dissemination of the results, even if the project formally ends on 31 August 2012, it has been agreed with CASPUR to continue carrying out the housing and maintenance of the EUPHORIC site until the end of 2012.

**Designing and publish the information leaflet**

In the first phase of activity, a project leaflet will be designed in order to give preliminary information to the hospitals included in the networks connected to the associated beneficiaries and cooperating with HOPE. In the second phase of the project, when the benchmarking function are accessible also for the other hospitals, a second leaflet will be prepared. Both leaflets will summarize the context and the objectives of EURHOBOP and will invite EU hospitals to participate in the project. Both leaflets, after approval by all the partners, will be translated by the partners into the languages spoken in the countries of all the partners participating in the project and will be made downloadable from the website homepage.

**Identify the stakeholders that will receive the final products of the project**

In order to enlarge the network for the dissemination, all the involved partners will be invited to establish useful contacts with other research projects both at national and European level and with all the interested stakeholders. Moreover, all the partners will be requested to circulate the EURHOBOP products within their institutional dissemination networks also taking into consideration the collection of feedback (comments, suggestions) received from the addressees.

Disseminating the results is a key issue for each project and targeting citizens and patients is imperative in the context of public health. Regarding this aim, the European Patients’ Forum is an optimal channel to reach patients and disseminate the results as well as the European Heart Network. In 2010 the WP 2 leader will contact both associations in order to study a useful way to cooperate on the dissemination.

To ensure the transfer of the results and instruments developed in the EURHOBOP project, direct e-mail communication (multilingual brochure and presentation letters) will be established with EU authorities, Public Health division authorities in the European Ministries of Health and, in cooperation with HOPE, with the cardiology departments in
hospitals of the participating countries. The scientific community will be informed also by means of presentations done in scientific Congresses and scientific publications submitted to peer review journals.

HOPE will also play a key role participating in the dissemination with their web of European country Federations of hospitals.

At the end of the project, a tutorial will also be setup in the web site, and CD or pendrives with the final benchmarking software for PC installation will be made available by the Project Coordinator. Personal demonstration sessions will be carried out by the partners on opportunistic basis with stakeholders showing their interest in the benchmarking system.

**Collaborating the Project coordinator in the preparation of a final brochure**

Besides the preparation of specific technical reports and presentations in conferences targeting the scientific community, a short brochure will be set up by the project leader in cooperation with the WP2 leader based on the contribution of all the partners. The brochure (approximately 5 pages) will describe the project and will focus on the achieved results. The aim of this activity will be to provide the partners with materials that will be also useful for local dissemination in the participating countries and to specifically target hospitals and patients.

The contents of the brochure, aimed at providing information to the policy makers and the health stakeholders, will be shared and agreed with EAHC. The brochure will be translated by the associated partners in the 6 languages spoken in their countries (Spanish, Italian, German, Finnish, Greek, and Portuguese). After approval by the Commission, it will be downloadable from the project website.

**Assisting the Project coordinator in promoting through the website the project final conference**

The final conference of the project will be held in Barcelona in August 2012. The website will provide a specific section to promote the conference and, after, to collect all the related useful material (e.g. programme, introductory poster, summary of the workshop, presentations, etc.)
Work package 3: Evaluation of the project

WP leader: Christa Meisinger HMGU

Background

Project evaluation is a systematic investigation of the worth or value of a project. It normally involves standard criteria, measures of success, or objectives that describe the value of a project. Project evaluation and project management are interrelated. Evaluation can help to complete a project successfully, provide evidence of successes and failures, suggest ways for improvements, and inform decisions about the future of current and planned projects. By evaluating a project, you monitor the process to ensure that appropriate procedures are in place for completing the project in time.

In the EURHOBOP project an internal and external evaluation will be conducted to monitor the project progress and to inform the project partners as well as an independent Scientific Advisor Committee about the status and output of the project.

Overall objective

The aims of the project evaluation are

- to support the project performance by monitoring the adherence to the timetable of the scheduled milestones and deliverables,
- to monitor the response of the invited European hospitals to register and use the benchmark functions once these function have been established,
- to provide data on the project performance for the external evaluation by a Scientific Advisor Committee

Specific tasks and methods

The Consortium agreement signed by all partners defines the tasks and responsibilities of the partners, as well as the consequences of non-compliance, and therefore constitutes the basis of the project evaluation.

Task 1: Monitoring of adherence to timetable, tasks and deliverables

At the end of the month in which the deliverable has to be completed the project partner responsible for the deliverable will receive an e-mail including a request whether and when the respective task was completed. In case the task was not fulfilled the project partner will be asked to name the reasons and the expected delay. This information will be forwarded to the project coordinator to decide on any actions that should be taken (e.g. telephone conference, meeting).
A Log file on the adherence to the timetable regarding the deliverables will be created which will be included in a summary report on the project status. This summary report will be prepared in 6 month intervals and distributed to the project coordinator and project partners.

<table>
<thead>
<tr>
<th>Deliverable No</th>
<th>Deliverable title</th>
<th>Deliverable date</th>
<th>Reminder and status evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td>Consortium agreement</td>
<td>M2</td>
<td>End of M2</td>
</tr>
<tr>
<td>D2</td>
<td>Protocols and data collection forms preparation</td>
<td>M4</td>
<td>End of M4</td>
</tr>
<tr>
<td>D4</td>
<td>First annual financial and technical interim report</td>
<td>M12</td>
<td>End of M12</td>
</tr>
<tr>
<td>D5</td>
<td>External Advisory Board evaluation</td>
<td>M22</td>
<td>End of M22</td>
</tr>
<tr>
<td>D6</td>
<td>Second annual financial and technical interim report</td>
<td>M24</td>
<td>End of M24</td>
</tr>
<tr>
<td>D7</td>
<td>Sex inequalities assessment</td>
<td>M28</td>
<td>End of M28</td>
</tr>
<tr>
<td>D9</td>
<td>Final outcome benchmarking functions</td>
<td>M30</td>
<td>End of M30</td>
</tr>
<tr>
<td>D10</td>
<td>Cost analysis</td>
<td>M32</td>
<td>End of M32</td>
</tr>
<tr>
<td>D12</td>
<td>Minutes and conference programmes for all EURHOBOP conferences</td>
<td>M38</td>
<td>End of M38</td>
</tr>
<tr>
<td>D13</td>
<td>Financial and technical final report</td>
<td>M36</td>
<td>End of M36</td>
</tr>
</tbody>
</table>

Furthermore, the active participation of all project partners regarding the collection of patient data in European hospitals will be followed. Every three months the number of collected cases per country will be summarized and the deviations from the intended number will be fed back to the respective project partners. A deviance < 10% is considered optimal performance. In case the deviance is ≥ 10% the project partner will be asked whether specific problems have occurred. This information will be forwarded to the project coordinator to decide on any actions that should be taken. A Log file on the adherence to the timetable regarding the data collection will be created which will be included in a summary report on the project status. This summary report will be prepared in 6 month intervals and distributed to the project coordinator and project partners.

**Task 2: Monitoring of the benchmarking functions**

Once the benchmarking functions are posted on the project web site a large sample of European hospitals will be invited to register and benchmark themselves. The
response rate will be used as an indicator of diffusion and impact on the target group. The response rate should exceed 25%. The response rates will be tracked. In case the target response rate will not be achieved another sample of hospitals will invited.

**Task 3: External evaluation by a Scientific Advisor Committee**

The external evaluation is planned to be conducted by an independent Scientific Advisor Committee including Public Health Authorities, clinicians, researchers and epidemiologists. The project progress will be assessed by judging the performance, achievements and task completion with standard forms. The Log files and summary reports mentioned above provide important information for the Scientific Advisor Committee. This evaluation is scheduled for the second year of the EURHOBOP project in order to apply corrective measures based on the Committees’ reports.
Work package 4: Hospital benchmarking function development and validation

WP leader: Jaume Marrugat IMAS-IMIM

Cardiovascular benchmarking

The European Union State members are concerned about the quality of health care and the possible inequalities among European citizens. Coronary heart disease is very frequent in Europe and is the origin of many admissions, patient management and procedure use.

A key instrument to improve the quality of health care consists of benchmarking the hospital performance. In EUPHORIC (DG SANCO2003 134) project we successfully wound up with a set of functions predictive of European Hospital performance in terms of management of coronary heart disease patients and some procedure used in their admission. The functions worked quite well in preliminary testing. Under the new EURHOBOP (EAHC 2008 13 12) project we will be validating the models on real life data from a large number of hospitals and testing the possibility of including other variables of severity.

Patients admitted for an acute coronary syndrome (ACS) in European hospitals receive a discharge diagnosis of myocardial infarction (MI) either with or without Q-wave in the electrocardiogram, or unstable angina (UA). ACS does not exist as an entry in the international classification of diseases (ICD), which is used in discharge diagnosis in European hospitals. MI and UA are easy to identify, clearly ICD-defined conditions with a high social impact, whose management includes a number of procedures that suit the objectives of the EUPHORIC study due to their availability in many hospitals in Europe and the fact that they are collected in existing monitoring systems.

Procedures to be analyzed

1. Coronary angiography;
2. Thrombolysis;
3. Percutaneous intervention;
4. General MI-UA patient management.

Outcome

In-hospital case-fatality after the procedure will be considered in the EURHOBOP study. Case-fatality represents a hard, standardized end-point that can be easily retrieved from medical records and administrative discharge records.
Patients

Two hundred consecutive patients with discharge diagnosis of MI or UA will be included in each participant hospital (10 hospitals per country). The sample size per hospital is 200 consecutive patients with acute coronary syndrome with or without ST segment elevation but with a discharge diagnosis of myocardial infarction or unstable angina will be retrospectively recruited. **No age limit is imposed.** This latter criterion to be revised when 40% of the sample has been recruited. The period of hospitalization should be 2008-2010 (but up to 2006 can be acceptable in small hospitals with little turn-over of coronary heart disease patients), as close to the present as possible to get the 200 expected patients.

In case of patients being referred to other hospitals, patients will be assigned to the hospital spent the longest time.

Given the difficulty of identifying patients admitted for non-cardiovascular diseases who develop a myocardial infarction or an unstable angina during hospitalization, and the low number that such subgroup of patients represents, each participant hospital may decide whether these patients are included or not.

The number of catheterization laboratory hospitals depends on the country, but we will accept between 3 and 7 out of the 10 hospitals with such on-site facilities.

An official invitation letter from EURHOBOP will be sent by WP2 leader to the PI in the hospital indicating the necessary information to be sent and the compensation in scientific and official acknowledgement of their contribution. See **Annex 5.**

A warning will be stated in the web site and manual for users that the models created in EURHOBOP are intended for European hospitals. Any other hospital in the world may obtain more imprecise or inaccurate results.

We will disregard readmissions during the period of recruitment due to:

- a) the low number of cases that will meet this characteristic,
- b) to the low impact that these few cases are going to have in the modelling, and
- c) to the considerable difficulties and effort that searching such cases may imply.

Data collection

**Patient characteristics**

Past history will be collected on the basis of the patients declaration. Clinical variables will be collected on the basis of clinician statements on the discharge letter.

See form for data collection, variable list and definition on **Annex 3.**

In some **countries with advanced networking systems,** the patient data collection may consist of selecting the data form the data bases accessible from public health
centers. All efforts required to adapt the anonimized data base provided to the IMAS-IMIM coordinating center will be done to the structure defined for the study. This task will be undertaken jointly by the partner and IMAS-IMIM personnel.

Data sources for patient characteristics

The basic source will be the discharge letter in ACS survivors. In hospitals with electronic registries data extractors may wish to check some data on emergency data electronic records or electronic medical record. Similarly some hospitals may have accessible electronic laboratory data records that may also be checked. In all cases the data sources have to be stated on the study data collection form, which will be electronic and accessible through the internet with the laptops with 3G or GPRS connection bought for the study.

The associated beneficiaries will adapt these source methods to their country and hospital characteristics, and will ensure the best possible data collection under their conditions. A close coordination with a collaborating cardiologist in each hospital is strongly recommended.

Data collection should be independent of the ward of patient admission. It is obvious that most patients with MI or UA will be admitted to a cardiology ward, but some elderly patients may be also admitted to internal medicine wards.

All necessary modification of the described strategy will be undertaken in each country to adapt to the local circumstances.

Country characteristics

We will use WHO web site data to collect the necessary country data characteristics (gross national product per capita, life expectancy at birth, age-standardized coronary heart disease mortality rates at [http://www.who.int/whosis/database/core/core_select.cfm](http://www.who.int/whosis/database/core/core_select.cfm)).

Hospital characteristics

A specific form will be used during the recruitment of hospitals to determine the participant hospital characteristics. See Annex 1.

Validation of models

We will use several risk functions with differing levels of complexity that were developed in the EUPHORIC DG SANCO project 2004-08 on ACS registries (some of which were not fully representative of Europe) to determine the quality of health care in MI or UA patients. Preliminary models were built in the EUPHORIC project based on 5
European acute coronary syndrome registries (31 countries) in which more than 250 European Hospitals participated. We introduced a number of variables at country level and at hospital level together with those at individual level. This multilevel analysis provides a percentile system with the interval of expected outcome values given the country, hospital and individual characteristics entered. In cooperation with HOPE, these models will be tested in the real context of a large set of European hospitals that will be allowed to register themselves in the restricted area of the website. Moreover these models need to be validated with as many real data sets of consecutive patients as possible. Given the relative complexity of obtaining these data, it would be impossible to cover 100% of hospitals of all European countries, the validation will be performed on a sample of 200 MI or UA patients consecutively admitted in approximately 10 hospitals (preferably 7 University and 3 non-University but according to each country characteristics the proportion may range from 7:3 to 3:7) from each participant country in EURHOBOP (i.e., Spain, Finland, Greece, Germany, France, Portugal and Italy), or approximately 14,000 patients in all. Compared to the initial proposal we have included a new partner from France to increase the number of hospitals and countries in the study.

The health system setting in each country varies: this is why not all collaborating hospitals will be associated partners, because possibly we will need no contact in such hospitals, given the fact that some countries have the required data already centralized in Public Health facilities (e.g., Finland).

A set of variables that determine patient outcome will be collected from medical records and from administrative discharge records (WP and from hospital managers or Cardiology Department themselves with summary data from their hospital and case fatality (WP8 HOPE) for Objective 1. A set of more complex data regarding severity and comorbidity of patients will also be collected from medical records for Objective 3. We will undertake separate analyses for men and women to ensure that potential inequalities are detected in use and outcome in these selected procedures and condition management for Objective 2.

Statistical analyses

Descriptive analyses will be performed at the individual, hospital and country levels. T-Student test and $\chi^2$ tests were used as appropriate to determine the relationship of the individual, hospital and country characteristics with the in-hospital case-fatality for each procedure.

We will perform a hierarchical logistic mixed regression model due to the natural clustering of the observations within hospitals and countries (statistical package R). We will fit models to estimate the odds ratios of case-fatality within 30 days of admission as a function of patient, hospital and country characteristics (fixed effects variables). We
will also include random hospital-specific and country-specific effect (random effects variables). This strategy accounts for within-hospital and within-country correlation of the observed outcomes and models the assumption that underlying differences in quality among the institutions and countries lead to systematic differences among outcomes.

Interaction and effect-modification of countries and hospitals is suggested to be tested during model fitting. The model needs to be as parsimonious as possible to prevent over-fitting and introducing variables that may not be available in all hospitals.
Step 1. Model Formulation
\[
\logit(p_{i(jk)}) = \mu + \tilde{x}_{i(jk)}\hat{\beta} + H_{j(k)} + C_k
\]
Where,
- \(i = 1, \ldots, n_{j(k)}\) is the patient index (nested in hospital)
- \(j = 1, \ldots, n_k\) is the hospital index (nested in country)
- \(k = 1, \ldots, K\) is the country index
- \(n_{j(k)}\) is the number of patients in the sample admitted in the j-th hospital of the k-th country
- \(n_k\) is the number of hospitals in the sample of the k-th country
- \(K\) is the number of countries in the sample
- \(\mu\) is the baseline risk in logit scale
- \(\tilde{x}_{i(jk)}\) is the vector of fixed effects variables (patient, hospitals and country characteristics).
- \(\hat{\beta}\) is the vector of fixed effects coefficients.
- \(H_{j(k)}\) is the hospital random effects under the assumption of independence which follows a normal distribution with zero mean and variance equal to \(\sigma_H^2\)
- \(C_k\) is the country random effects under the assumption of independence which follows a normal distribution with zero mean and variance equal to \(\sigma_C^2\).
- \(\logit(p) = \log\left(\frac{p}{1-p}\right)\) is the logit function.
- \(p_{i(jk)} = \Pr(y_{i(jk)} | \tilde{x}_{i(jk)}, H_{j(k)}, C_k)\) is the probability of event for the i-th patient admitted at j-th hospital in k-th country, given the fixed effects variables and hospital and country random effects.
- \(y_{i(jk)}\) is the binary outcome variable for the patient i(jk)-th, coded 1 (Yes) or 0 (No).

Step 2. Modelling risk-standardized case-fatality for each hospital
The 30-day in-hospital case-fatality rate of a particular hospital is predicted as follows:
\[
p_o = \frac{1}{1 + e^{-\eta}}
\]
Where,

- \( \eta = \mu + x_0 \hat{\beta} + \hat{C}_0 + q \) is the linear predictor
- \( q \) is a random value of a normal distribution of zero mean and variance equal to \( \sigma_q^2 \)
- \( x_0 \) is the vector of the average patient and country characteristics corresponding to a particular hospital.

From then on, two cases are distinguished,

1. the hospital belongs to a country used to fit the model,
2. the hospital does not belong to a country used to fit the model.

**Case a)**

- \( \hat{C}_0 \) is the “Empirical Bayes Estimate” of the country random effect where the hospital belongs to.
- \( \sigma_q^2 \) is equal to \( \hat{\sigma}_H^2 \) (see Step 1)

**Case b)**

- \( \hat{C}_0 \) is fixed to zero.
- \( \sigma_q^2 \) is equal to \( \hat{\sigma}_H^2 \) plus \( \hat{\sigma}_C^2 \) (see Step 1)

And, \( \hat{\mu} \), \( \hat{\beta} \), \( \hat{\sigma}_H^2 \) and \( \hat{\sigma}_C^2 \) are the estimated values of \( \mu \), \( \beta \), \( \sigma_H^2 \) and \( \sigma_C^2 \) obtained from the model fitted previously.

The application of these hierarchical models allows us to assessing the performance of a specific-hospital given its own characteristics, and those of the admitted patients and of the country in which the hospital is located. From these data, the model predicts the number of expected deaths at a “reference” hospital with the same characteristics of the specific-hospital and estimated the percentiles of the adjusted-risk case-fatality distribution.

To assess the model performance we will compute the area under the ROC curve, finally.

Statistical analysis will be performed with R Statistical Package (R Foundation for Statistical Computing, Vienna, Austria Version 2.0).

New GLM multilevel models will be fitted for each procedure, and the beta estimates of in-hospital case-fatality compared to those obtained in the previous EUHORIC project with data from non-representative ACS registries.
Benchmarking hospitals

The benchmarking will be established in terms of procedure use and outcome rate by comparing a given hospital with the general distribution of all hospitals (percentiles with individual ranking will be provided anonymously for each hospital).

Data extraction procedures. Content:

Schedule for the data extractors training course
Summary
   General objective
   Methods and means
Methodology
   Cardiovascular benchmarking
   List of partners involved
   Study population
Initial study management concepts
   Arrangement with representatives of candidate hospitals
   Patient inclusion
   Confidential data
   Patient data collection form
   Patient identification
   Data extractor identification
Variable definition
   Patient identification variable
   Diagnosis variables
   Basic data
   Previous history
   Admission data
   Procedure variables
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   2. How can I identify the patients in the EURHOBOP study?
   3. Where can I find the information required in the forms?
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   5. How to send the form
### Schedule for the data extractors training course

<table>
<thead>
<tr>
<th>Day</th>
<th>Hour</th>
<th>Content</th>
<th>Lecturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>25th January</td>
<td>09:30</td>
<td>Brief Introduction: EURHOBOP Project</td>
<td>Jaume Marrugat</td>
</tr>
<tr>
<td></td>
<td>10:00</td>
<td>Preliminary Concepts on Study Management</td>
<td>Maria Grau</td>
</tr>
<tr>
<td></td>
<td>10:30</td>
<td>Variable Definition I</td>
<td>Maria Grau</td>
</tr>
<tr>
<td></td>
<td>11:30</td>
<td>COFFEE BREAK</td>
<td></td>
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<tr>
<td></td>
<td>12:00</td>
<td>Variable Definition II</td>
<td>Maria Grau</td>
</tr>
<tr>
<td></td>
<td>12:30</td>
<td>Roadmap for Data Extraction</td>
<td>Maria Grau</td>
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<td>14:00</td>
<td>LUNCH</td>
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<td></td>
<td>15:00</td>
<td>Workshop</td>
<td>Paula Cabero, Maria Grau, Ruth Martí, Martina Sidera, Cristina Soler</td>
</tr>
<tr>
<td>26th January</td>
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<td>Summary</td>
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<td>COFFEE BREAK</td>
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<td></td>
<td>11:45</td>
<td>Concluding Remarks</td>
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### Summary

**General Objective**

EURHOBOP seeks to validate a set of predictive mathematical functions that include indicators of in-hospital case fatality outcome to assess the quality of myocardial infarction (MI) or unstable angina (UA) patient management and of the following procedures: coronary angiography, thrombolysis, and percutaneous intervention. The indicators will be adjusted for patient, hospital and country characteristics and will permit hospitals to benchmark their performance in these procedures.

**Methods and Means**

We will consider in-hospital case-fatality as the outcome indicator in patients admitted for an acute coronary syndrome (ACS) who receive a discharge diagnosis of MI or unstable angina (UA) and undergo coronary angiography, thrombolysis, or percutaneous revascularisation (angioplasty with or without stenting) for general MI and UA patient management. We will validate several risk functions (GLM multilevel models) with different levels of adjustment, developed in the EUPHORIC DG SANCO project (2004-08), and we will develop new ones. The validation will be performed on a
sample of 200 consecutive MI or UA patients from 10 hospitals per participant country (in total, 70 hospitals and 14,000 patients).

The expected results consist of a set of hospital-validated mathematical functions suitable for European hospital benchmarking of cardiovascular disease management performance and for European citizens to determine their risk of in-hospital death when submitted to these procedures.

**Methodology**

**Cardiovascular Benchmarking**

Patients admitted for an acute coronary syndrome (ACS) receive a discharge diagnosis of myocardial infarction (MI) either with or without Q-wave in the electrocardiogram, or unstable angina (UA). ACS does not exist as an entry in the international classification of diseases (ICD), which is used in discharge diagnosis in European hospitals. MI and UA are easily identified, clearly ICD-defined conditions with a high social impact, whose management includes a number of procedures.

**List of Partners Involved**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Institution</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMAS – IMIM</td>
<td>Institut Municipal d’Assistència Sanitària - Institut Municipal d’Investigació Médica</td>
<td>Spain</td>
</tr>
<tr>
<td></td>
<td>Municipal Institute for Health Services/Municipal Institute for Medical Research</td>
<td></td>
</tr>
<tr>
<td>DEASL</td>
<td>Department of Epidemiology, Health Authority RM-E</td>
<td>Italy</td>
</tr>
<tr>
<td>FMUP</td>
<td>School of Medicine, Universidade do Porto</td>
<td>Portugal</td>
</tr>
<tr>
<td>HMGU</td>
<td>Helmholtz Zentrum München – Deutsches Forschungszentrum für Gesundheit und Umwelt GmbH</td>
<td>Germany</td>
</tr>
<tr>
<td>THL</td>
<td>Health Services Research, National Research and Development Centre for Welfare and Health</td>
<td>Finland</td>
</tr>
<tr>
<td>AEPMCV</td>
<td>Department of Epidemiology, Toulouse University School of Medicine</td>
<td>France</td>
</tr>
<tr>
<td>ISS</td>
<td>Superiore/National(??) Institute of Health, WHERE?</td>
<td>Italy</td>
</tr>
<tr>
<td>HOPE</td>
<td>European Hospital and Healthcare Federation</td>
<td>Belgium</td>
</tr>
<tr>
<td>HCS – ATTIKON</td>
<td>Hellenic Cardiologic Society – Attikon University Hospital</td>
<td>Greece</td>
</tr>
</tbody>
</table>
Study Population
Each participating country will recruit 2,000 admitted patients (200 consecutive patients in 10 different hospitals, preferably 7 University and 3 non-University).

Initial study management concepts

Arrangement with Representatives of Candidate Hospitals
EURHOBOP Researchers should contact candidate hospitals representatives and explain to them the objectives and methodology of the study. Once the hospital representatives have agreed to participate in the Study, the EURHOBOP Researchers should complete the “Collaborating Hospital Characteristics Data Collection Form” (Annex 1).

Death Registry
The main objective of the EURHOBOP Study is to classify European hospitals according to their performance, and therefore individuals diagnosed with ACS who die before discharge are of particular interest. EURHOBOP researchers and data extractors should be thoroughly knowledgeable about the procedures used to register in-hospital deaths.

Patient Inclusion
Patients to be included must be consecutive and diagnosed with ACS. There are no age or severity restrictions. Inclusion of the required 200 patients may require different periods of time depending on the Hospital’s care level, reference population and activity.

All 200 patients will be investigated, including those who die before hospital discharge.

Confidential Data
To guarantee participants confidentiality, all identifying data will be dissociated. For this purpose, data extractors should register each patient’s name and surname, medical record number, sex, age, and date of admission in an independent table (see Annex 2), one for each hospital. These registries will remain at the participating hospitals.

Patient Data Collection Form
When a country’s full list of collaborating hospitals has been forwarded to the coordinator and to Marina Torre (ISS partner), hospital codes will be assigned and patient data collection can begin, using the Patient Data Collection Form (Annex 3).

Please extract data from (in order of preference): 1) letter of discharge, 2) computer records from emergency room 3) computer records from admission, or 4) medical records.
The form contains two variable categories:

- Black variables. The fields should be filled in for all patients (200 per hospital).
- Red variables. The fields should be filled in only for a 10% of the sample (the 20 most recent patients in each hospital).

**Patient Identification**

All patients in the EURHOBOP Project will be identified by a string code consisting of three elements:

- **Country Code.** Each participant country will be identified by a number from 1 to 7.
- **Hospital Code.** Every hospital will require a unique code, typically 1 to 10, but up to 20 to cover possible dropouts or additional recruitment centers.
- **Patient ID.** Consecutive patients will be numbered from 1 to 200 in each hospital. When data extractors are unable to identify a particular patient (e.g. typo in patient’s last name), this patient will be replaced by a new one with the same ID.

<table>
<thead>
<tr>
<th>Country</th>
<th>Code</th>
<th>Hospitals (example)</th>
<th>Code</th>
<th>Patients (example)</th>
<th>Code</th>
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<td>Timothy Lovejoy</td>
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<td>Blue Hospital</td>
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<td>Seymour Skinner</td>
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<td>Purple Hospital</td>
<td>06</td>
<td>Clancy Wiggum</td>
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<td></td>
<td>Brown Hospital</td>
<td>09</td>
<td>Marvin Monroe</td>
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<td>Pink Hospital</td>
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<td>Selma Bouvier</td>
<td>010</td>
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</table>

Example. Patient Code 510008 = Patient Troy McClure from the Pink Hospital in Germany

**Data Extractor Identification**

Data extractors will be identified by an alphanumeric code that must be included in all submitted forms as a proof of authenticity. If this field is empty or contains a nonexistent code, the system will reject the submission.
Variable Definition

Patient Identification Variable

Country
Choose your country: Spain, Greece, Italy, Portugal, Germany, Finland, or France.

Hospital code
Enter the code (typically 1-10) you have assigned to the hospital in which you are extracting data.

Patient ID
You may construct this code in any way that permits accurate access to the original patient data in the event of a query from the coordination center’s data management department.

Medical record extractor
Enter your own assigned personal code.

Diagnosis Variables

Type of Acute Coronary Syndrome on admission
Choose Non ST Elevation Acute Coronary Syndrome (Non-STEACS) or ST Elevation Acute Coronary Syndrome (STEACS), referring to electrocardiographic characteristics observed on patient arrival to emergency room. This finding guides clinicians in the best choices for patients according to the presence or not of these characteristics. If this information is not found in the records and you have made every effort to determine ACS type for this patient, choose “Not stated”.

Discharge diagnosis
Choose myocardial infarction (MI) or unstable angina (UA). No other diagnosis is relevant to this study.

Basic Data

Age
State the age in years of the patient on admission (e.g., 59 years, 11 months=59 years).

Sex
Record the patient’s weight in kg. If not stated in any source, choose “Not stated”.

Weight
Record the patient’s weight in kg. If not stated in any source, choose “Not stated”.

Height
Record the patient’s height in cm. If not stated in any source, choose “Not stated”.

BMI
Record the patient’s body mass index determined as weight divided by squared height in kg/cm. Fill in with four numbers: two integers and two decimals.

Note: Never type the decimal point. Use “zero” as a placeholder, as appropriate. Do not estimate BMI. If not stated in any source, choose “Not stated”.


Obesity
This condition is typically stated if it pertains. Collect the history of this condition as “Yes”, “No” or “Not stated”.

Previous History

Smoking
This condition is typically stated if it pertains. Collect the history of this condition as “Yes” for current smokers, “No” for never smokers or smokers >1 year, or “Not stated”. Ex-smokers <1 year will be considered as “Current smokers”.

Diabetic
This condition is typically specified if it pertains. Collect the history of this condition as “Yes, type I”, “Yes, type II”, “Yes, type not stated”, “No”, or “Not stated”.

Diabetic
This condition is typically stated if it pertains. Collect the history of this condition as “Yes, treated”, “Yes, not treated”, “Yes, treatment not stated”, “No” or “Not stated”.

Past history of CV disease
This condition is typically specified if it pertains. Collect the history of this condition as “MI”, “Other CHD”, “Stroke”, “PAD”, “Previous PCI”, “Previous CABG”, “Previous heart failure”, “Oral anticoagulation”, “Atrial fibrillation”, “None” or “Not stated”.

Renal failure, Alzheimer/ other dementia
These conditions are typically stated if pertinent. Collect the history of these conditions as “Yes”, “No” or “Not stated”.

Other serious illness
These conditions are typically stated if pertinent. Type the considered illness.

Admission Data

Coming from
Choose whether the patient came from home, nursing home/residential care center, other hospital, primary care or somewhere else. If not stated in any source, choose “Not stated”.

Date of admission
Provide this date in day/month/year format (dd/mm/yy) to compute the length of stay.

Heart rate and Systolic blood pressure on admission
These data are very easy to locate, particularly if emergency room records are computerized. However, they are rarely found on discharge letters (otherwise the preferred data source). Record the corresponding data or choose “Not stated” as appropriate.

Acute pulmonary edema on admission
This is an expression of a degree of cardiac failure of considerable importance and severity.

Note: Usually if a patient has developed this condition before admission, it is so stated; the opposite is not true. Therefore, the option “No” will be seldom used. Choose “Yes”, “No” or “Not stated” as appropriate.
**Cardiogenic shock on admissions**
This is an expression of cardiac failure of great severity.

**Note:** Usually if a patient has developed this condition before admission, it is so stated; the opposite is not true. Therefore, the option “No” will be seldom used. Choose “Yes”, “No” or “Not stated” as appropriate.

**Initial Creatinine**
The preferred laboratory results are the values obtained on admission, usually stated on the emergency room records but computerized laboratory records also could be checked. The letter of discharge might include values for admission or the earliest taken if no other value is provided. Fill in the values under the appropriate units (mg/dl or μmol/l).
Fill in with four digits: when mg/dl units are used, two integers and two decimals; when values are expressed in mol/l, three integers and one decimal.
Never type the decimal point. If no value is available, choose “Not stated”.

**Initial Glucose**
The preferred laboratory results are the values obtained on admission, usually stated on the emergency room records but computerized laboratory records also could be checked. The letter of discharge might include values for admission or the earliest taken if no other value is provided.
Fill in with two digits: one integer and one decimal. Never type the decimal point.
Fill in the values under the appropriate units (mg/dl or mmol/l). If no value is available, choose “Not stated”.

**Initial Hemoglobin**
The preferred laboratory results are the values obtained on admission, usually stated on the emergency room records but computerized laboratory records also could be checked. The letter of discharge might include values for admission or the earliest taken if no other value is provided. Fill in with three digits: two integers and one decimal.
Never type the decimal point. If no value is available, choose “Not stated”.

**Procedures Variables**

**Thrombolysis**
Collect this procedure as “Yes, prehospital”, “Yes, in hospital”, “Yes, in other hospital”, “Yes, but unknown place of administration” or “No”.

**Coronary angiography**
Collect this procedure if used on the patient during the hospital stay as “Yes”, or enter “No”.

**Percutaneous intervention (PCI)**
Collect this procedure if used on the patient during the hospital stay as “Primary”, “Rescue”, “Other urgent [PCI] during same hospitalization”, “Elective” when time elapsed between admission and this procedure is longer than 72 hours, or enter “No”.

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If any PCI has been done, collect the next two variables

**Time after admission**
Collect the elapsed time between admission and the percutaneous intervention. Fill in the values in hours and minutes. If no value is available, choose “Not stated”.

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Type of PCI
This is a multiple choice variable. Collect the type of PCI (if done) as “Bare metal stent”, “Drug-eluting stent”, “POBA”, “Thromboaspiration” or “Not stated”.
Fill in the values in hours and minutes. If no value is available, choose “Not Stated”.

Coronary artery by-pass surgery, Cardiac ultrasound examination (echocardiogram), Intravascular ultrasound (IVUS), Fractional flow reserve (FFR), Optical coherence tomography (OCT), Intracardiac defibrillator (ICD), Intra-aortic balloon pump (IABP)
Collect these procedures as “Yes”, “No” or “Not stated”.

Note: Usually if these procedures have been used on a patient during hospitalization, it is so stated; the opposite is not true. Therefore, the option “No” will be seldom used. Choose “Yes”, “No” or “Not stated” as appropriate

Severity indicators & complications during hospitalization

TIMI risk (0-14) and GRACE (0-372) scores
Record the values if available on the documents examined; otherwise, mark “Not stated”.

Q-wave in the evolving electrocardiograms
Record whether patient had a Q-wave in any electrocardiogram subsequent to the emergency room electrocardiography. A diagnosis of unstable angina means that this variable must be disregarded.

Note: Mark “Unstable angina” to indicate the reason for not providing this datum.

Anterior ECG MI location
The area of myocardial infarction that died during the heart attack can be anatomically located by the electrocardiographic characteristics i.e., ST elevation higher than 1mm observed in at least two precordial leads. Usually this location is described in the letter of discharge. Choose “Yes”, “No” or “Not stated” as appropriate.

Troponin
Troponin reference values could vary between hospitals. Record the corresponding value, the upper limit considered in the hospital, and the type of troponin measured (I or T), or choose “Not stated” as appropriate.

Left systolic ejection fraction
The ejection fraction is the fraction of blood pumped out of a ventricle with each heartbeat. Record the corresponding value (%) and choose “Normal (>55)”, “Slightly depressed (45-55)”, “Moderately depressed (35-45)”, “Severely depressed (<35)” or “Not stated” as appropriate.

Acute pulmonary edema during hospital stay
This is an expression of cardiac failure of great severity. Usually if a patient has developed this condition during the hospital stay, it is so stated; again, the opposite is not true. Therefore, the option “No” will be seldom used. Choose “Yes”, “No” or “Not stated” as appropriate.

Cardiogenic shock during hospital stay
This is an expression of cardiac failure of great severity. Usually if a patient has developed this condition during the hospital stay, it is so stated; the opposite is not true.
Therefore, the option “No” will be seldom used. Choose “Yes”, “No” or “Not stated” as appropriate.

**Cardiac arrest, Acute renal failure, Reinfarction, Stroke/TIA, Intracranial bleeding**

These are three common ACS complications of considerable importance and severity. Usually if a patient has developed this condition during the hospital stay, it is so stated; the opposite is not true. Therefore, the option “No” will be seldom used. Choose “Yes”, “No” or “Not stated” as appropriate.

**Bleeding with a drop in hemoglobin >50g/L**

Usually if a patient has developed clinically overt signs of bleeding associated with a drop in hemoglobin >50g/L during the hospital stay, it is so stated; the opposite is not true. Therefore, the option “No” will be seldom used. Choose “Yes”, “No” or “Not stated” as appropriate.

**Bleeding with a drop in hemoglobin >30g/L but <50g/L**

Usually if a patient has developed clinically overt signs of bleeding associated with a drop in hemoglobin >30g/L and <50g/L during the hospital stay, it is so stated; again, the opposite is not true. Therefore, the option “No” will be seldom used. Choose “Yes”, “No” or “Not stated” as appropriate.

**Days in Coronary Care Unit**

Provide the number of days in the Coronary Care Unit to compute the length of stay.

**Days in Intensive Care Unit**

Provide the number of days in the Intensive Care Unit to compute the length of stay.

**Discharge**

**Date of discharge/death**

Provide this date in day/month/year format (dd/mm/yy) to compute the length of stay. Double-check that Date of admission + total Days in Coronary/Intensive Care Unit does not exceed Date of discharge/death.

Note that in case of patient death, the date of death (dd/mm/yy) is required.

**Discharge vital status**

This information refers to survival status. Choose **alive** or **dead**.

**Note:** Filing of discharge reports may vary by hospital. “Not stated” should be an extremely rare entry, to be used only after making every effort to determine the patient’s survival status from available hospital data.

**Discharge to**

Choose the place where the patient goes at discharge: home, nursing home, other hospital, or dead, in case of patient death.

**Data sources**

**Data source(s) screened**

Indicate all the data sources you checked to complete the Data Form for this patient: letter of discharge, computer records from emergency room, computer medical records, medical records on paper, and/or computerized laboratory records.
**Roadmap for data extraction**

1. **Where can I find the on-line forms?**
You are expected to complete both the Hospital Characteristics and the Patient Characteristics at the EUPHORIC (http://www.euphoric-project.eu/) web site. You will need to login, and then go to the “EURHOBOP Home” menu under the “EURHOBOP Bridge” heading on your left.

To choose an option, just click on it. If you need to complete the form by hand, use a black pencil or black ballpoint pen.

Data extractors will be assigned a personal ID and a password that will be required to enter the data.

2. **How can I identify the patients in the EURHOBOP Study?**
Patients will be identified in the EURHOBOP Study by the country code, the hospital code and the patient code (see page 6, “Patient Identification” Section).

Before filling in the form, the patient should be registered (age, sex, name, surname and data of admission) in the Confidential Data table (Annex 2).

3. **Where can I find the information required in the forms?**
Please extract data from (in order of preference): 1) letter of discharge, 2) computer records from emergency room 3) computer records from admission, or 4) medical records.

If all mandatory fields could not be completed using data from the letter of discharge, the data extractors should use the emergency room computer records for this purpose.

The computer records from admission should be checked if any mandatory information has not been found in the preferred data sources.

Finally, the medical records on paper are the last source of data that should be consulted.

**Note:** The data source field should always indicate all the data sources that have been checked to find the required information.

4. **Quality Control**
To ensure quality control, some impossible combinations must be avoided.

Please check carefully:

1. All the fields in the form should be filled:
   a. If all the mandatory fields can be filled with the information in the letter of discharge, the rest of the fields can be filled as “not stated” and the form will be accepted.
b. If a mandatory field cannot be filled from the information included in the letter of discharge, data extractors must check the remaining data sources in the correct order (see page 7, “Sources of data” Section).

c. In the mandatory fields, “Not stated” will only be acceptable once all four data sources have been checked.

2. When a patient has been diagnosed with unstable angina (“Discharge Diagnosis”), unstable angina must be marked in both “Q-wave in the evolving ECG” and “Anterior ECG MI location”.

3. “Data source” must always be filled with the sources checked, even when the required variable is “not stated”.

4. “Date of admission” is always before “Date of discharge”.

5. “Date of admission” plus “Days in Coronary Unit” or “Days in Intensive Care Unit” is always before “Date of discharge”.

6. If “Discharge vital status” is “Alive” the variable “Discharge to” will always be “Home” or “Nursing home” or “Other hospital”.

7. If “Discharge vital status” is “Dead” the variable “Discharge to” will always be “Dead”.

8. Note that when a PCI is stated, a coronary angiography is also to be marked because a PCI cannot be done without a coronary angiography. The opposite is not true.

5. How to send the form

Press “Print and Send” button when all the mandatory fields have been filled.

At this moment the submission process will start. Once the submission has been completed, a confirmation screen appears and an automatic PDF file with the completed form will be generated. Remember that this PDF will serve as a proof that could be used when the sending procedure fails (Annex 4).

To obtain this PDF file for each submitted form, the software to manage PDF documents must be installed in your computer. It can get for free in the internet. We strongly recommend selecting this PDF software as the default printer in your computer.
COLLABORATING HOSPITAL CHARACTERISTICS COLLECTION FORM

COUNTRY: ☐ Finland ☐ France ☐ Germany ☐ Greece ☐ Italy ☐ Portugal ☐ Spain

Provide a unique code for this hospital (1 to 20) in your country: ______

Name of contact person: ____________________________________________

e-mail: __________________________________________________________

Hospital Name: ____________________________________________________

Address: __________________________________________________________

Street: ____________________________________________________________

Postal Code: ________

City: ______________________________________________________________

Telephone: ______________________

Web site: __________________________________________________________

Total number of beds: ________ Patients discharged in the cardiology dept. in last year: ________

Coronary Care Unit: ☐ Yes ☐ No

Intensive Care Unit: ☐ Yes ☐ No

Catheterization Laboratory: ☐ Around the clock ☐ Working time ☐ On call ☐ No

Cardiac surgery: ☐ Around the clock ☐ Working time ☐ On call ☐ No

University Hospital: ☐ Yes ☐ No

Other Investigators in this hospital (maximum 3):

1. ________________________________________________________________

2. ________________________________________________________________

3. ________________________________________________________________

Main data sources used:

☐ Letter of discharge

☐ Computer records from emergency room

☐ Computer medical records

☐ Medical records on paper

☐ Computerized laboratory record
### Annex 2. Confidential Data Table

*European Hospital Benchmarking by Outcomes in Acute Coronary Syndrome Processes. EURHOBOP Project*

<table>
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<tr>
<th>Country # (1 – 7)</th>
<th>Hospital # (1 – 20)</th>
<th>Patient # (1 – 200)</th>
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Annex 3. Patient Data Collection Form

EURHOBOP Project
European Hospital Benchmarking by Outcomes in Acute Coronary Syndrome Processes

PATIENT DATA COLLECTION FORM

Country: ☐ Finland ☐ France ☐ Germany ☐ Greece ☐ Italy ☐ Portugal ☐ Spain
Hospital code: _______ Medical record extractor: _______
Patient ID: _______
Type of Acute Coronary Syndrome on admission: ☐ STEACS ☐ Non-STEACS ☐ Non-classifiable ☐ Not stated
Discharge diagnosis: ☐ Myocardial Infarction ☐ Unstable Angina

Basic data

Age: _______ years
Sex: ☐ Male ☐ Female
Weight: _______ kg ☐ Not stated
Height: _______ cm ☐ Not stated
BMI: _______ ☐ Not stated ☐ Obese: ☐ Yes ☐ No ☐ Not stated

Previous history

Smoking: ☐ Yes ☐ No ☐ Not stated
Diabetic: ☐ Yes, type I ☐ Yes, type II ☐ Yes, type not stated ☐ No ☐ Not stated
Hypertension: ☐ Yes, treated ☐ Yes, not treated ☐ Yes, treatment not stated ☐ No ☐ Not stated
Past history of CV disease: ☐ MI ☐ Other CHD ☐ Stroke ☐ PAD ☐ Previous PCI ☐ Previous CABG ☐ Previous heart failure ☐ Oral anticoag. ☐ Atrial fibrillation ☐ None ☐ Not stated
Renal failure: ☐ Yes ☐ No ☐ Not stated
Alzheimer/Other dementia: ☐ Yes ☐ No ☐ Not stated
Other serious illness, describe: ____________________________

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Admission data

Coming from:  ○ Home  ○ Nursing home  ○ Primary care center  ○ Other hospital  ○ Other place  ○ Not stated

Date of admission:  [ ] [ ] [ ] [ ]

Heart rate on admission:  ___ bpm  ○ Not stated

Systolic blood pressure on admission:  ___ mm Hg  ○ Not stated

Acute pulmonary edema on admission:  ○ Yes  ○ No  ○ Not stated

Cardiogenic shock on admission:  ○ Yes  ○ No  ○ Not stated

Initial Creatinine:  ___ mg/dl  ___ μmol/l  ○ Not stated

Initial Glucose:  ___ mg/dl  ___ mmol/l  ○ Not stated

Initial Haemoglobin:  ___ g/l  ○ Not stated

Procedures used during hospitalization

Thrombolysis:  ○ Yes, prehospital  ○ Yes, in other hospital  ○ Yes, in hospital  ○ Yes, unknown place of administration  ○ No

Coronary angiography:  ○ Yes  ○ No

Percutaneous intervention (PCI):  ○ Primary  ○ Rescue  ○ Other urgent during same hospitalization  ○ Elective  ○ No

Time after admission:  [ ] [ ]  ○ Not stated

If any PCI is done:  ○ Bare-metal stent  ○ Drug-eluting stent  ○ POBA  ○ Thrombectomy  ○ Not stated

Coronary artery bypass surgery:  ○ Yes  ○ No  ○ Not stated

Cardiac ultrasound examination (echocardiogram):  ○ Yes  ○ No  ○ Not stated

Intravascular ultrasound (IVUS):  ○ Yes  ○ No  ○ Not stated

Fractional flow reserve (FFR):  ○ Yes  ○ No  ○ Not stated

Optical coherence tomography (OCT):  ○ Yes  ○ No  ○ Not stated

Intracardiac defibrillator (ICD):  ○ Yes  ○ No  ○ Not stated

Intra-aortic balloon pump (IABP):  ○ Yes  ○ No  ○ Not stated

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Severity indicators and complications during hospitalization

TIMI (0-14): ______ or GRACE risk score (0-372): ______ or Not stated

Q-wave in the evolving ECG: ○ Yes ○ No ○ Unstable angina ○ Not stated

Anterior ST elevation: ○ Yes ○ No ○ Not stated

Troponin peak: ______, ______ Upper limit value for normality: ______, ______ ○ T ○ I ○ Not stated

Left systolic ejection fraction: ______% ○ Normal ○ Slightly depressed ○ Moderately depressed ○ Severely depressed ○ Not stated

Acute pulmonary edema: ○ Yes ○ No ○ Not stated

Cardiogenic shock: ○ Yes ○ No ○ Not stated

Cardiac arrest: ○ Yes ○ No ○ Not stated

Acute renal failure: ○ Yes ○ No ○ Not stated

Reinfarction: ○ Yes ○ No ○ Not stated

Stroke / TIA: ○ Yes ○ No ○ Not stated

Intracranial bleeding: ○ Yes ○ No ○ Not stated

Bleeding with a drop in haemoglobin >50 g/L: ○ Yes ○ No ○ Not stated

Bleeding with a drop in haemoglobin >30 g/L but <50 g/L: ○ Yes ○ No ○ Not stated

Days in Coronary Care Unit: ______

Days in Intensive Care Unit: ______

Discharge

Date of discharge/death: ______/______/______

Discharge vital status: ○ Alive ○ Dead

Discharge to: ○ Home ○ Nursing home ○ Other hospital ○ Dead ○ Not stated

Data sources screened:

Letter of discharge: ○ Computerized ○ Central registry ○ Medical record ○ No

Computer records from emergency room: ○ Yes ○ No

Computer medical records: ○ Yes ○ No

Medical records on paper: ○ Yes ○ No

Computerized laboratory record: ○ Yes ○ No

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Annex 4. Visual Aid

STEP 1
Please go to the EUPHORIC website (www.euphoric-project.eu)

STEP 2
You will find the Username and Password fields in the lower part of the web page. Enter your personal data and press “Log in” button.

STEP 3
At this moment, a new menu called “EURHOBOP Bridge” appears in the left upper part of the web page.
Press the subheading “EURHOBOP Home”.
Annex 5. Official invitation letter from EURHOBOP

Barcelona, month .......... day........., 2010

Dr. .................
Cardiology Department
Hospital.....
Address
City
Postcode
Country

Dear Colleague,

As the Coordinator of the European Project EURHOBOP (European Hospital Benchmarking by Outcomes in Acute Coronary Syndrome-, of the European Agency for Health and Consumers (EAHC), contract no 20081312) I take a genuine pleasure in welcoming you as a collaborating partner in our project.

EURHOBOP is focused on the development of a group of mathematical functions aimed at benchmarking the European hospitals based on the hospital mortality observed during the use of some diagnostic and therapeutic procedures (coronariography, thrombolysis, intra-coronary percutaneous intervention), and in myocardial infarction and unstable angina management. Functions are adjusted by country, hospital, and patients characteristics.

For this project we need the collaboration of the Cardiology Department in 70 European hospitals. We are very pleased to include yours in this task which will consist of reviewing 200 medical discharge letters of patients consecutively admitted for an acute coronary syndrome receiving a discharge diagnosis of myocardial infarction, or unstable angina. A trained medical record extractor will come to your hospital to develop this task, in which we will greatly appreciate that you assist him or her.

This letter is a formal invitation to be part as a Collaborating Partner of the EURHOBOP Project. Your contribution will be fully acknowledged in all European Commission documents and publications.

Dr. Jaume Marrugat MD PhD FESC
Program of Research in Inflammatory and Cardiovascular Disorders (RICAD)
Institut Municipal d'Investigació Mèdia (IMIM–Hospital del Mar)
Barcelona Biomedical Research Park
Tel +34 93 3160710 ; Fax +34 93 3160796
www.regicor.org; www.redheracles.net; www.imim.es; www.eurhobop.eu
Work package 5: Analysis of the availability of severity measurements in administrative data

WP leader: Jean Ferrières AEPMCV

List of partners involved
AEPMCV (WP Leader), IMAS-IMIM, DEASL, FMUP, HMGU, THL, HCS-ATTIKON, HOPE

Objectives
To explore the feasibility of collecting and the relevance of including various indicators of severity in the benchmarking models.

Description of the work package
A set of clinical and more complex variables on comorbidity and severity allowing the calculation of risk scores such as TIMI score, will be consider for the prediction of in-hospital mortality: Killip class on arrival, heart failure during admission, weight, heart rate and systolic blood pressure on admission, left bundle branch block, and anterior ST elevation.

Administrative discharge data from those patients for whom medical records are extracted, will also be obtained whenever possible.

We will develop a set of benchmarking functions for cardiovascular procedures with increasing complexity (i.e., number of variables with patient risk scores) taking into account the variability in severity and comorbidity characteristics that can be obtained in medical records. We will use general linear multivariate models to obtain adjusted estimates of the coefficients for the variables considered (i.e., in-hospital mortality).

Deliverables and links with other workpackages
Report: Outcome benchmarking functions interim and final reports D4 D6 D8.

Variables to be considered
The evaluation of the severity of an acute coronary syndrome is based on the collection of clinical, biological and enzymatic parameters. Angiographic variables are also sometimes recorded if the patient is admitted in a hospital with an on-site catheterization laboratory. Clinical parameters represent the medical history of the patient, and his/her co-morbidities and current clinical situation. Biological and
enzymatic variables are related to the collection of plasma creatinine levels and plasma values of cardiac biomarkers such as troponin, CRP or NT-ProBNP.

The clinical and biological parameters (and angiographic variables for CADILLAC) collected can be tested individually or as a part of established scores, among which the most widely used are the TIMI score, the CADILLAC score, the PAMI score and the GRACE score.

The TIMI score (0–14) is based on the collection of the following variables: age 65-74/≥75 years; systolic blood pressure <100 mm Hg; heart rate >100 beats/min; Killip classification 2-4; anterior STEMI or left branch bundle block; diabetes mellitus, hypertension, or angina pectoris; weight <67 kg and time to treatment >4 h.

The CADILLAC score (0–18) is based on the collection of the following variables: baseline left ventricle ejection fraction <40%; renal insufficiency; Killip classification II-IV; final TIMI flow 0-2; age >65 years; anemia (defined as baseline hematocrit <39% for men and <36% for women); 3-Vessel disease.

The PAMI score (0–15) is based on the collection of the following variables: age >75 years; age 65-75 years; Killip classification >I; heart rate >100 beats/min; diabetes mellitus; anterior STEMI or left branch bundle block.

The GRACE score (0–372) is based on the collection of the following variables: Age (yrs) [<30, 30-39, 40-49, 50-59, 60-69, 70-79, 80-89, ≥90]; heart rate (beats/min) [<50, 50-69, 70-89, 90-109, 110-149, 150-199, >200]; systolic blood pressure (mm Hg) [<80, 80-99, 100-119, 120-139, 140-159, 160-199, >200]; creatinine (mg/dl) [0-0.39, 0.4-0.79, 0.8-1.19, 1.2-1.59, 1.6-1.99, 2-3.99, >4]; Killip classification; cardiac arrest at admission; increased cardiac markers; ST-Segment deviation.

All the variables necessary to the calculation of the scores are generally found in medical records which are stored away from the departments of cardiology. In the discharge letter, we will find the most important parameters for prognosis estimation and long-term management including left ejection fraction, number of diseased coronary arteries, probability of having severe arrhythmias and use of recommended secondary preventive drugs. However, in the discharge letter, the precise variables necessary to the establishment of the scores are not always present or are recorded with an imprecise terminology.

In the EURHOBOP project, a patient data collection form was created and includes a large number of the clinical and biological parameters necessary to the calculation of the risk scores. Indeed, one will find in the patient data collection form, age, heart rate on admission, systolic blood pressure on admission, acute pulmonary oedema during admission, cardiogenic shock during admission, Killip class, heart failure during admission, left bundle branch block, anterior ECG myocardial infarction location and troponin peak. In this EURHOBOP patient data collection form, we will obtain
information on weight, creatinine, glucose and presence of diabetes, hypertension or a past history of cardiovascular disease.

In the ideal situation where all of the the variables listed in the patient data collection form of the EURHOBOP project can be collected, we will not have any problem to establish risk estimates according patients’ characteristics. In other cases, we will assess whether the most significant variables for prognosis assessment are collected in the EURHOBOP project. These most relevant variables are older age, higher Killip class, elevated heart rate, lower systolic blood pressure and the anterior location of an acute myocardial infarction. We will also study the proportion of patients for whom information on personal history of coronary disease, weight, creatinine, previous history of diabetes, hypertension or cardiovascular disease can be collected.

On the whole, the evaluation of the severity of acute coronary syndromes is difficult in the “real world”. The objective of this working package is to know whether a minimum set of cardiac parameters is sufficient to accurately estimate the risk of in-hospital mortality. We will compare the performance of a restricted number of variables obtained from the data included in the discharge letters with the performance of a more widened number of variables also obtained from discharge letters, with respect to the vital status. It is indeed possible that a restricted number of clinical and biological variables could be sufficient to correctly predict the risk of in-hospital mortality in patients presenting with an acute coronary syndrome.
Work Package 6: Gender inequalities assessment
("Effect modification by gender in outcome studies")

WP leader: Marina Davoli DEASL

Background


In recent studies higher mortality among women have been explained by a different distribution of risk factors between genders (review by Berger et al 2009, Dey et al 2009: GRACE; Vaccarino et al 1995 – review 1966-1994, Suessenbacher et al 2008, Berger et al 2006). These factors comprise both patient characteristics (age, ACS severity, presence of co-morbidities) and health care related issues (access to treatment and treatment effectiveness).

Patient characteristics

Generally, women presenting with ACS are older than men, and the prevalence of co-morbidities such as diabetes and hypertension is higher among females.

A recent pooled analysis of data from 11 previous studies on ACS patients (Berger J et al 2009) found higher 30-day mortality among women. However, the gender difference disappeared, when accounting for clinical differences at presentation (higher female mortality in STEMI and lower in NSTEMI and unstable angina), severity of angiographically documented disease (women more often had non-obstructive and less often had 2-vessel and 3-vessel coronary disease, regardless of ACS type), and co-morbidities (more frequent among women). These results confirm previous observations of a significant gender by type of coronary syndrome interaction (Hochmann et al 1999).

An outcome study performed by the Italian Network on Acute Coronary Syndromes (IN-ACS) demonstrated effect modification by gender and clinical presentation. Female gender was associated with a reduced risk of dying in the first 30 days after the event (OR = 0.58, 95% CI 0.35-0.94). (http://www.anmco.it/inacsout/).

A significant interaction between diabetes and gender on mortality after AMI in patients < 65 years was detected in a recent Canadian study (Ouhoummane et al 2009);
women with diabetes had a 52% higher mortality than men after controlling for co-
variables.

**Healthcare related factors**

**Access**

Differences in access to coronary care units among patients with acute myocardial infarction were found in a Rome cohort, with poorer care associated to old, ill, and poor people. Women had a significantly lower probability of accessing specialised care than men (OR=0.73; 95%CI: 0.64-0.84) (Ancona C et al BMC Health Services Research 2004). Gender differences in access to optimal care were observed in several studies, with lower probability of admittance to specialised wards and invasive strategies (Herlitz et al 2009; Halvorsen et al 2009, El-Menyar et al 2009, Suessenbacher et al 2008; Jneid et al 2008; Peterson et al 2008; Lee et al 2008; Srichaiveth et al 2007).

**Secondary prevention**

Results on the use of evidence based drug treatment after ACS are controversial, but several studies found female gender to be a negative independent predictor of optimal medical therapy after ACS (Tuppin et al 2009, Dey et al 2008; Peterson et al 2008; Vermeer et al 2008, Lee et al 2008, Yan et al 2007). A recent study performed by the Department of Epidemiology (DEASL) found gender differences in secondary drug prevention treatment after IMA. Women had a lower probability to be treated with evidence based combined drug therapy than men; adjusting for age and comorbidities the gender difference decreased and was not statistically significant any longer (Kirchmayer et al 2009).

**Effectiveness**

The role of gender in the effectiveness of treatment has been discussed controversially. A recent pooled analysis using data from 10 RCTs to compare the effectiveness of CABG with PCI reports that treatment effect was not modified by gender (Hlatky et al 2009). Tillmanns et al 2005 found that after successful PCI women have a long-term prognosis comparable or even better than men.

A Danish study reports fewer benefit for women with unstable angina and NSTEMI MI from routine, early, invasive treatment (Holmvang et al 2008). This result was confirmed by a review and meta-analysis of clinical trials comparing the effects of an invasive vs conservative strategy in women and men with NSTE ACS which found no gender difference for high-risk patients, while benefit of invasive strategy in low-risk females was not proven. In a prospective registry analysis female gender was found to
be an independent predictor of death after implantation of drug eluting stents (Berenguer et al 2009).

Rationale
Evidence on the role of gender on ACS outcomes is controversial and does not allow for a conclusive evaluation to date. An important limitation is that most evidence comes from pooled analysis of RCTs, which however under-represent women and people with co-morbidities and is limited in terms of medium/long-term outcomes. Therefore, more evidence is needed from observational (effectiveness) studies, which represent the target population of the treatment in real practice. The large database (about 14000 individual records) which will be collected from 70 hospitals in 7 European countries within the Eurhobop project offers the unique opportunity to investigate the potential gender differences in ACS outcome studies in different temporal and geographical settings.

Objectives
To determine whether ACS outcomes differ by gender by different exposures and, in particular, investigate the role of gender as an effect modifier of ACS’s outcomes.

Specific objectives
Specifically:

1. To compare ACS outcomes by gender (overall/country specific)
2. To compare ACS outcomes in different hospitals (benchmarking) by gender
3. To compare access to PCI by gender (overall/country specific)
Methods

Case definition

- enrolment of hospitals (comprising all wards)
- enrolment of all consecutive admissions (no selection)
- enrolment according to admission to the first hospital, excluding patients with less than 24 hours of hospital stay (except for death)
- ACS: all diagnoses positions, excluding patients with major surgical procedures in first position, using ICD codes (definition STEMI / NSTEMI / unstable angina)
- admission period: 1/1/2008-31/12/2008 (for small hospitals going back in time in order to enrol 200 patients)

Data availability from different participants

200 patients from 10 hospitals in each participating site: about 14,000 patients expected

Objective 1. To compare ACS outcomes by gender (overall/country specific)

Exposure: gender

Outcomes:

- In-hospital case fatality
- MACCE (mortality, cardio and cerebrovascular events) at different time-intervals, if available (3, 6, 12, 24 months)

Potential effect modifiers: country (or groups of countries, e.g. northern/southern Europe)

Potential confounders:

First step

- Socio demographic characteristics
- Severity (to be defined)
- Comorbidities (to be defined)

Second step

- Variables considered at the first step
- Type of hospital ward (specialised or not)
- Treatment (PTCA, thrombolysis, pharmacological therapies)
Analysis

Statistical modelling will be different according to the study outcome: multilevel logistic models for the “in-hospital case fatality”, multilevel survival models for the “MACCE” outcome. Furthermore, analyses will be performed for the entire dataset, and by country (or groups of countries).

The effect of country (or groups of countries) on hospital-mortality will be tested by fitting multivariate logistic regression models within the multi-level framework, which incorporates both individual-level covariates (socio-demographic characteristics, acute and chronic severity indicators, type of treatment) at the first step, and country (type of hospital, type of ward, etc.) at the second step. The set of individual-level and hospital-level confounders will be chosen based on a priori judgement for some variables and empirical stepwise procedures for others. Crude and adjusted odds ratios will be calculated and converted in risk ratios using conventional formulas.

The effect of country (or groups of countries) on hospital-MACCE association will be performed by fitting multivariate Cox proportional-hazards regression models within the multi-level framework, incorporating the same individual- and hospital-level variables as for the logistic models. Check for the proportionality assumption will be performed via plotting of Schoenfeld residuals, and alternative approaches (i.e. adjusted Kaplan-Meier survival curves) will be implemented in case of rejection of the proportionality assumption.

Crude and adjusted hazard ratios will be estimated from Cox models, or adjusted country-level survival curves will be plotted.

**Objective 2. To compare ACS outcomes in different hospitals (benchmarking) by**

This objective follows the methodology of the main project analysis (WP 4/ WP 8). Benchmarking will be performed for male and female cases.

**Exposure:** hospital of care

**Outcomes:**

- In-hospital case fatality
- MACCE (mortality, cardio and cerebrovascular events) at different time-intervals, if available (3, 6, 12, 24 months)

**Potential effect modifier:** Gender
Potential confounders:

First step

- Socio demographic characteristics
- Severity (to be defined)
- Comorbidities (to be defined)

Second step

- Variables considered at the first step
- Type of hospital ward (specialised or not)
- Treatment (PTCA, thrombolysis, pharmacological therapies)

Analysis:

The effect of gender on hospital-mortality association will be tested by fitting multivariate logistic regression models within the multi-level framework, which incorporates both individual-level covariates (socio-demographic characteristics, acute and chronic severity indicators, type of treatment) at the first step, and hospital-level factors (type of hospital, type of ward, etc.) at the second step. The set of individual-level and hospital-level confounders will be chosen based on a priori judgement for some variables and empirical stepwise procedures for others. Crude and adjusted odds ratios will be calculated and converted in risk ratios using conventional formulas.

The effect of gender on hospital-MACCE association will be performed by fitting multivariate Cox proportional-hazards regression models within the multi-level framework, incorporating the same individual- and hospital-level variables as for the logistic models. Check for the proportionality assumption will be performed via plotting of Schoenfeld residuals, and alternative approaches (i.e. adjusted Kaplan-Meier survival curves) will be implemented in case of rejection of the proportionality assumption.

Crude and adjusted hazard ratios will be estimated from Cox models, or adjusted hospital-level survival curves will be plotted.

Objective 3. To compare access to PCI by gender (overall/country specific)

Exposure: PCI

Outcomes:

- In-hospital case fatality
- MACCE (mortality, cardio and cerebrovascular events) at different time-intervals, if available (3, 6, 12, 24 months)
Potential effect modifier: gender

Potential confounders:

First step

- Socio demographic characteristics
- Severity (to be defined)
- Comorbidities (to be defined)

Second step

- Variables considered at the first step
- Type of hospital ward (specialised or not)
- Treatment (PTCA, thrombolysis, pharmacological therapies)

Analysis:

Analysis will be performed differently according to the study outcome: multilevel logistic models for the “in-hospital case fatality” outcome, multilevel survival models for the “MACCE” outcome.

Procedures for the selection of confounders and checking of model assumptions will be based on the same criteria developed for Objectives 1 and 2.

The analysis of the effect modification of gender in the PCI access-outcome association will be performed by adding an interaction term between the exposure variable and gender in the multivariate model, and by checking for significance of the effect modification on the basis of the interaction p-value.
References


Work package 7: Cost analysis of procedures.

WP leader: Unto Häkkinen THL

Objectives

- Generally: To analyze the cost of managing myocardial infarction (MI) and unstable angina pectoris (UA)
- More precisely: to compare procedure cost by hospital complexity level, by country and by performance in terms of outcome achieved. In addition, to take into account the patients’ severity characteristics.
- The aim is to calculate the cost of hospital care for selected coronary patients and procedures and relate them to short term outcome (in hospital mortality)

Background

An international cost comparison in health care includes many important topics and steps that must be considered (Mogyorosy and Smith 2005). In this study the main aim is to compare the cost of hospital care of MI and UA patients and relate the costs to outcomes. This means that we need to collect background characteristics, outcome data and cost of care from the same patients.

We will compare the cost of hospital episodes using mainly bottom-up approach. This can be made using two alternative approaches. The cost analysis will be rather easy in those hospitals that have developed cost accounting systems that include cost information at individual patient level. However this is not reality in many European countries.

Another approach is based on identifying resource items used and selecting the unit for measurement (hospital days, specific procedures, use of drugs etc.). After that we need to specify how to place monetary value for the resource items and calculate the cost of hospital episodes. In addition, we need to be sure that the content of a hospital episode is comparable between hospitals. The next step is to express the costs using a single currency and taking into account the price differences between the countries. Finally we need to consider risk adjustment i.e. to take into account the case-mix differences between the patients.

Main phases of the study

The study will be made in several phases:

1. Clarifying the objectives and definitions for the cost study and requirements for patient level data collection. Spring 2010.
2. In this phase the objectives and definitions of the study will be clarified. This can be made after the patient questionnaire is finalized. At this moment it seems that the study will be done using two samples. The first sample include those hospitals (at least some hospitals in Spain and Finland) in which patient level data (from questionnaire) can be linked with patient level cost information. Second sample will include all hospitals of the Eurhobop and is based on more aggregate level cost information.


4. We will send a questionnaire to each participating hospital whether hospitals have cost information at individual patient level and if this can this be linked to patients included in the project data base, as well as availability of more aggregate level of cost information resource items (such as cost of procedures and intensive care days) included in our database.


6. Based on information from second phase we will develop protocols for measuring cost of hospital episodes for the two samples.

7. Collecting cost data from those hospitals from where it is available. Spring 2011.

8. Using the protocols developed in previous phases we collect the cost data.


10. The analysis of costs include several stages such as measurement of the cost of episodes, taking into account price differences between countries, taking into account differences in patient characteristics etc. The latter can be made by estimating cost function using appropriate econometric methods that take into account the functional form (linear, log, box-cox transformation, GLM modelling) and distribution (skewed and censoring) of the dependent variable, while controlling for various aspects of patient selection.


Reference

Work package 8: Benchmarking testing with hospital real life data

WP leader: Pascal Garel HOPE

The overall objective of this work package is to determine whether the distribution of expected outcomes fits the observed distribution. To do so a large number of hospitals is needed.

Two actions should be built in parallel: to identify the ways to reach hospitals; to prepare specific arguments to convince them to contribute.

The ways to reach hospitals

The end result requested is a decision made by Hospital Managers and/or Head of cardiology department to allow or to ask staff to provide information.

In order to obtain this decision in a maximum of hospitals, the approach is here to gain access to the opinion leaders at European, national and regional levels so that they would forward a positive opinion among hospitals/Departments.

HOPE will approach the European Union of Medical Specialists to get access to the European Society of Cardiology and then National societies of cardiology (December 2009).

HOPE will request the help of EURHOBOP partners linked with the European Society of Cardiology (January/February 2010).

HOPE will work with each of the partners in the seven countries to identify a specific strategy to attract hospitals other than the 10 (January/February 2010).

HOPE will work with each of its members individually to define the best approach to reach hospitals in the country (January/February 2010).

HOPE will contact the European Heart Network (January 2010) to present the project and to see to which extend they could help.

Working with other projects is also a way to reach hospitals, as well as a way to coordinate activities, since all of them are involving individual hospitals. A specific relation should be built with each of them.

- DUQuE (in which HOPE is a partner), will be contacted by HOPE since they also are targeting, among others, cardio-vascular issues. The connection with the previous project MARQuIS might also be important as individual hospitals were involved. HOPE will raise it at the next meeting (February 2010).
• EUNetPaS (in which HOPE is a partner) is a way to reach member states from the Patient safety angle. HOPE will find an appropriate way to share views. HOPE will raise it at the next meeting (January 2010).

• PATH (to which HOPE is linked) has a network of several hundred of hospitals. HOPE will contact them (January 2010) to evaluate possibilities of collaboration.

• For PROSAFE (http://prosafe.marionegri.it/homepage.aspx) a contact should be made using the EURHOBOP network.

The arguments and tools for promotion

The differences between the two sets of hospitals have to be taken into consideration. The 70 hospitals that will participate with extensive data (selected in the 7 partner countries) are well covered. All the others that wish to participate with their own data directly on the website need a slightly different approach.

The present leaflet covers all arguments needed to convince hospitals: improving the quality of care; tackling inequalities; participating to a European project.

On this basis, HOPE prepared the following information that will be used in letters and articles, addressing specifically the hospitals that wish to participate with their own data directly on the website.

“EURHOBOP, the EURopean HOsptal Benchmarking by Outcomes in acute coronary syndrome Processes is looking for partner hospitals all over Europe.

What do you get by joining EURHOBOP?

• You will be able to determine the in-hospital Acute Coronary Syndrome Processes case-fatality risk for individual data

• You will be able to benchmark your hospital with aggregated data but on a confidential basis

• You will be at the forefront of European innovation in quality of care by contributing to develop a valid standardized monitoring system.

What do you need to do?

Simply to register on www.eurhobop.eu and provide information"