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EU Public Health Outcome Research and Indicators Collection

EUPHORIC Project

Grant Agreement n° 2003134

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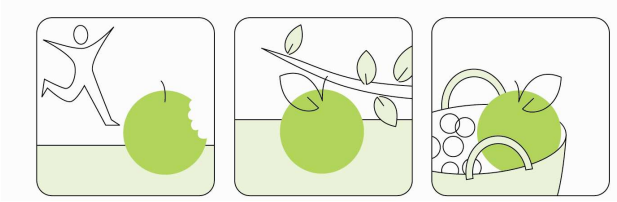
Final Report

15/12/2004 – 14/12/2008

May 2009



EUPHORIC Project

MAIN BENEFICIARY

Istituto Superiore di Sanità, *Italy*

ASSOCIATED BENEFICIARIES

EFORT/EAR Verein zur Unterstützung der Tätigkeit von nationalen Endoprothesenregistern, *Austria*

Sosiaali- ja terveysalan tutkimus- ja kehittämiskeskus, *Finland*

National and Kapodistrian University of Athens, *Greece*

ASL RM E Department of Epidemiology, *Italy*

Institut Municipal d'Assistència Sanitària, *Spain*

Karolinska Institutet, *Sweden*

COLLABORATING PARTNERS

National Center of Public Health Protection, *Bulgaria*

Catalan Agency for Health Technology Assessment and Research, *Spain*

Slovak Arthroplasty Register, *Slovak Republic*

Arthroplasty Register Tyrol, *Austria*

Ludwig Boltzmann Institut Health Technology Assessment, *Austria*

French Society of Orthopaedic and Trauma Surgery, *France*

BQS Bundesgeschäftsstelle Qualitätssicherung gGmbH, *Germany*

Israel Society for the Prevention of Heart Attacks at NCRI, *Israel*

The report was prepared by Marina Torre[1] based on the contributions submitted by each partner.

[1] Istituto Superiore di Sanità, Italy

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PROJECT FACT SHEET

Contract number: 2003134

Proposal title: EU Public Health Outcome Research and Indicators Collection Project

Acronym: EUPHORIC

Starting date: 15/12/2004

Duration of the project: 3 years + 1 year extension

Reporting period: 15/12/2004 – 14/12/2008

Main partner: ISS – Istituto Superiore di Sanità, *Italy*

Number of associated partners: 7

1) EFORT/EAR Verein zur Unterstützung der Tätigkeit von nationalen Endoprothesenregistern, *Austria (*EAR)
2) Sosiaali- ja terveysalan tutkimus- ja kehittämiskeskus, *Finland (*STAKES)
3) National and Kapodistrian University of Athens, *Greece (*NKUA)
4) Genetics Research Institute ONLUS, *Italy* (until 6 February 2008) (GRI)
5) ASL RM E Department of Epidemiology, *Italy* (DEASL)
6) Institut Municipal d'Assistència Sanitària, *Spain* (IMAS-IMIM)
7) Karolinska Institutet, *Sweden* (KI)

Number of collaborating partners: 8

1) National Center of Public Health Protection, *Bulgaria* (NCPHP)
2) Catalan Agency for Health Technology Assessment and Research, *Spain* (CAHTA)
3) Arthroplasty Register Tyrol, *Austria* (TILAK)
4) Ludwig Boltzmann Institut Health Technology Assessment, *Austria* (LBI HTA)
5) French Society of Orthopaedic and Trauma Surgery, *France* (SOFCOT)
6) Slovak Arthroplasty Register, *Slovak Republic* (SAR)
7) BQS Bundesgeschäftsstelle Qualitätssicherung gGmbH, *Germany* (BQS)
8) Israel Society for the Prevention of Heart Attacks at NCRI, *Israel* (ISPHA)

Total amount of the project: 2,788,105.28 Euro

EC co-funding : 1,500,000.00 Euro

1. EXECUTIVE SUMMARY

Background

The importance of outcome research has become evident as a means to promote best practice and control health expenditure. Monitoring efficiency and efficacy in the health field is acknowledged by most of the EU countries as a guarantee of quality care and outcome measurement. It is a tool to evaluate health care quality, which represents one of the most important areas of interest both at a national and international level. Initiatives have started at the European level to regulate and promote patient circulation as clearly stated in the Patient Rights Charters. These actions require objective and reliable indicators. To this purpose the use of common methodologies is imperative.

General and specific objectives

EUPHORIC was a multidisciplinary project oriented to policy authorities and policy makers that aimed at building a consortium of participating countries in order to:

- cooperate on benchmarking the outcomes of selected health performances
- exchange information on quality standards, best practice and effectiveness in public health by developing and maintaining EU networks
- verify the hypothesis that the possibility of developing common outcome indicators in Europe exists
- identify common EU elements that are suitable for a political EU platform oriented at best practice guarantees for EU citizens.

Specific aims of the proposed project were to:

- set up a high quality framework – consortium
- collect detailed information on health outcome indicators
- develop a standardized methodology
- assess quality of care of selected health procedures
- provide objective, transparent, high quality and standardized information that is easily accessible to users (doctors, health staff, health administration, decision makers, policy makers, EU people)
- provide assistance to EU countries for the development and implementation of a common monitoring system of standardized outcome indicators with a view to eventually creating common public health planning in Europe
- investigate the validity of routinely collected data.

Since the activities of the project were focussed on health outcome indicators, they could be considered complementary to others already carried out by projects related to health indicators like ECHIM and OECD.

Organization of the project

The project was guided by a network of 15 institutions from 10 European countries (Austria, Bulgaria, Finland, France, Germany, Greece, Italy, Slovak, Spain, and Sweden) and Israel. The network played a crucial role in the development of a joint effort to provide a valuable source of information.

From the beginning, the project suffered from several administrative problems (resignation of the project leader, withdrawal of two partners) that were solved with the signing of two amendments on 26 January 2007 (appointment of the new project leader, inclusion of partner EFORT-EAR) and on 9 February 2009 (reorganization of the budget). The project was divided into three phases:

- Survey: to make an inventory of outcome research studies and outcome indicators in participating countries
- Pilot: to test selected indicators in participating countries
- Dissemination: to make results available to EU authorities, institutions, study participants and citizens on a multi-language website.

In order to facilitate the writing up of standardized reports and to guarantee the comparability of the interim reports, in 2007, the EUPHORIC project was reorganized in the following six work packages (WP), each one being linked to specific objectives and activities:

1. Project management
2. Dissemination strategy
3. Liaison with other EU projects, EU programmes and health stakeholders
4. Indicators development
5. Indicators testing in currently running register databases
   5.1. Cardiovascular pilot
   5.2. Orthopaedic pilot
   5.3. Risk adjustment and statistics pilot
6. Setting up and maintaining an indicators database

Activities undertaken

WP 1 Management of the project (Resp. MB ISS)

Setting up the consortium; coordination of communication among partners and between the EUPHORIC consortium and DG SANCO; organization of coordination and core working group meetings; inclusion of new collaborating partners; cooperation with ECHIM and submission of some selected indicators to be considered for the short list (Deliverable n. 4); preparation of the evaluation plan (Deliverable n. 3); drawing up of the interim and final reports.

WP 2 Dissemination strategy (Resp. MB ISS)

Preparation of the dissemination policy and of the dissemination plan (Deliverable n. 5); identification of the project; design of a website and selection of the technological partner (CASPUR); design and publication of the information leaflet (translated in 11 languages); publication of the newsletter; preparation of selected documents requested by DG SANCO; organization of the final workshop; preparation of a brochure (translated in 11 languages); preparation of the short document “EUPHORIC at a glance” (translated in 11 languages); preparation of a video; organization of a virtual table of discussion; preparation of a press kit.

WP 3 Liaisons with other EU projects, EU programmes and health stakeholders (Resp. AB STAKES)

Contacts with the following projects were established: ECHIM, eHID, EUnetHTA, EUGLOREH, OECD (Health Quality Indicators Project), HDP, and European Patients' Forum.

WP 4 Indicators development (Resp. MB ISS)

Definition of the list of outcome indicators and assessment of the current situation about outcome indicators in the participant countries (Deliverable n. 1); preparation of the detailed sheets of the collected outcome indicators (Deliverable n. 6); preparation of a glossary on "Best practices/Benchmarking" (Deliverable n. 2); selection of diseases and procedures to test some indicators in the experimental phase (pilot).

WP 5 Development of adverse outcome risk indicators in real clinical and register databases and their possible use in administrative systematic databases (pilot)

The pilot focussed its activities on acute coronary syndrome (WP 5.1) and joint arthroplasty (WP 5.2) using the available sources of information, such as routinely collected data, clinical data, and registers. A specific work package (WP 5.3) relevant to risk adjustment and statistics was included as a support to both pilots.

WP 5.1 Cardiovascular pilot (Resp. AB IMAS-IMIM)

Appointment of Prof. Jaume Marrugat (IMAS-IMIM) as cardiovascular pilot leader; elaboration of the cardiovascular pilot protocol (Deliverable n. 8); cooperation with ISPHA and inclusion of databases (MASCARA Study 2005, EURO Heart Survey 2000, EURO Heart Survey 2005, ACSIS 2004 and 2006); selection of variables to be included in the model; elaboration of the mathematical functions; cooperation with CASPUR to implement the benchmarking function on the private area of the website; cooperation with partner STAKES for a preliminary validation of the functions; development and updating of a systematic review of the literature on the efficacy of GPIIb-IIIa inhibitors in ACS (Deliverable n. 7); preparation of the final report (Deliverable n. 8.1).

WP 5.2 Orthopaedic pilot (Resp. AB EAR)

Appointment of Dr. Gerold Labek (EAR) as orthopaedic pilot leader; elaboration of the orthopaedic pilot protocol (Deliverable n. 9); preparation of the final report (Deliverable n. 9.1); description of the Swedish and Finnish outcome measurement systems (Deliverable n. 9.2 and Deliverable n. 9.3); development of a tool to characterize registers (by CP LBI HTA, Deliverable n. 9.4); analysis of rationale and value to link outcome and economic data in a register (Deliverable n. 9.5 and Deliverable n. 9.6); link discharge records with outcome register data (Deliverable n. 9.7); study a hypothesis concerning follow up of artificial joint implants (Deliverable n. 9.8); description of arthroplasty register projects in Europe and comparison of clinical studies and register results. All the results and the technical reports will be published only after approval by DG SANCO and DG Enterprise.

WP 5.3 Use of the available sources of information in participant countries in order to develop a standardized statistical methodology for comparative evaluation of outcomes (risk adjustment and statistics pilot) (Resp. AB DEASL)

Appointment of Dr. Danilo Fusco (DEASL) as risk adjustment and statistics pilot leader; elaboration of the risk adjustment and statistics pilot protocol (Deliverable n. 12); description of the methodologies related to risk adjustment procedures (Deliverable n. 10); collection of information on health care information systems and registers as well as on clinical variables and statistical procedures used in the cardiovascular registers and on details about the arthroplasty registers in the EUPHORIC participating countries (Deliverable n. 12.1, Deliverable n. 12.2); cooperation with the EPIC-Greece study (Deliverable n. 12.3); comparative evaluation of

outcomes between register-based or information system-based risk adjustment models (Deliverable n. 12.4); definition of extended protocols for some selected indicators (AMI and hip fracture) (Deliverable n. 12.5); development of a statistical procedure to identify the real confounding variables in the comparative evaluation of outcomes (Deliverable n. 12.6).

WP 6 Setting up and maintaining the indicators database (Resp. MB ISS)

Setting up the web-based database for the indicators and for the data sources available in the participating countries. Setting up the electronic input data form. Input of the data collected during the survey. Validation of the questionnaires by partners. Guideline to correctly input the indicators data on the database (Deliverable n. 11).

Outcomes and deliverables achieved

List of main outcomes

- Set up the website
- List of health outcome indicators
- Structured information about data sources available in the participating countries
- Cardiovascular benchmarking tool
- Assessment of arthroplasty registers
- Definition of statistical procedures for a comparative evaluation of outcomes using risk adjustment methodologies
- Preparation of a set of tools that are useful for the dissemination of the results.

List of deliverables

Deliverable n. 1	Survey: the first phase of the project	Dec 08	Rel.3
Deliverable n. 2	Glossary	Jul 08	Rel.2
Deliverable n. 3	Evaluation Plan	Feb 09	Rel.2
Deliverable n. 4	Indicators submitted to ECHIM to be considered in the short list	Nov 07	Rel.1
Deliverable n. 5	Dissemination Plan	Mar 09	Rel.2
Deliverable n. 6	Detailed sheets of the collected outcome indicators (long list)	Dec 08	Rel.2
Deliverable n. 7	Platelet glycoprotein IIb/IIIa blockers for percutaneous coronary intervention, and as initial treatment in Non-ST segment elevation Acute Coronary Syndromes. (Systematic review of the literature)	Nov 07	Rel.1
Deliverable n. 8	Protocol for the Cardiovascular Pilot Study	Jun 08	Rel.2
Deliverable n. 8.1	Cardiovascular Pilot Study – Final technical report	Feb 09	Rel.1
Deliverable n. 9	Protocol for the Orthopaedic Pilot Study	Sep 07	Rel.1
Deliverable n. 9.1	Orthopaedic Pilot Study – Final technical report	Apr 09	Rel.1
Deliverable n. 9.2	Quality Registers in Finland	Mar 09	Rel.1
Deliverable n. 9.3	Quality Registers in Sweden	Feb 09	Rel.1
Deliverable n. 9.4	Characterising Registries for reviewing purposes	Jan 09	Rel.1
Deliverable n. 9.5	Register-based Documentation of Economic and Administrative Data and Linkage to Outcome measurement – Report by the Romanian National Arthroplasty Register	Feb 09	Rel.1
Deliverable n. 9.6	Economic data concerning Arthroplasty and Register data from Emilia Romagna	Dec 08	Rel.1

Deliverable n. 9.7	Potential Use of Discharge Records in Outcome Measurement and Link with Data from Outcome Registers based on the example of Arthroplasty	Feb 09	Rel.1
Deliverable n. 9.8	Data Mining and Arthroplasty Register datasets	Feb 09	Rel.1
Deliverable n. 10	Risk adjustment methodologies	Feb 08	Rel.1
Deliverable n. 11	Web-based Questionnaire: completion guideline	Sep 08	Rel.2
Deliverable n. 12	Protocol for the risk adjustment and statistics workpackage	Jul 08	Rel.1
Deliverable n. 12.1	Information on national hospital data collections in the EU states participating in the EUPHORIC project	Jan 09	Rel.1
Deliverable n. 12.2	Information from cardiovascular and arthroplasty registries	Jan 09	Rel.1
Deliverable n. 12.3	Identifying cardiovascular diseases (CVDs) by using one or more information sources	Jan 09	Rel.1
Deliverable n. 12.4	Identifying the clinical variables determining the difference in terms of comparative evaluation of outcomes between register-based or information system-based risk adjustment models	Jan 09	Rel.1
Deliverable n. 12.5	Extended protocols	Jan 09	Rel.1
Deliverable n. 12.6	Identification and definition of risk factors for comparative evaluation of outcomes - A “change-in” estimate procedure	Jan 09	Rel.1
Deliverable n. 12.7	Statistical procedures for comparative evaluation of outcomes	Jan 09	Rel.1

Activities planned for the next period

Implementation of the dissemination plan (Deliverable n. 5); reorganization of the website home page by uploading the recently developed dissemination tools (brochure, video, the short document “EUPHORIC at a glance”) after approval by the Commission; cooperation with HOPE in the dissemination of the results achieved in the cardiovascular pilot and in bridging EUPHORIC with future projects.

Conclusions and recommendations

In spite of a difficult start and several administrative problems that prevented its regular development, EUPHORIC worked at a steady rate since 2007 and was able to keep to schedule in order to achieve the stated objectives and also deliver some products, unforeseen in the original contract, giving added value to the whole project.

Establishing a high quality framework consortium that considers all the interested stakeholders is a key issue for a project. Patients are the real target of every action in public health and their inclusion, through patient associations, should be considered from the beginning of the project. Even if the cooperation between EUPHORIC and the European Patients’ Forum representatives was limited to the last year of activity, very useful input was given to the virtual table of discussion and cooperation was established to implement the dissemination.

The aim of the first phase of the project, the survey, was to define a list of outcome indicators and to collect information about the sources of data available in the participating countries in order to compute the indicators included in the list. On the basis of the data available in the first year of activity, i.e. in 2005, EUPHORIC defined a list of 54 outcome indicators in nine areas of disease and integrated the work carried out in other projects, such as ECHIM. For each health outcome indicator, detailed information was collected and also uploaded in a searchable database available on the project website. Information related to the sources available in the participating countries was also organized in a web-based database. The

list of indicators, the selected areas of disease and the description of the data sources available were essential for the further design of the pilot. However, if used now they would need to be updated taking into account a careful definition of the diagnoses, procedures, coding and registration differences between the countries.

The second phase of the project, the pilot, provided interesting results in the cardiovascular and orthopaedic areas and verified the hypothesis that the possibility of developing common outcome indicators in Europe exists. Efforts were made to identify common European elements suitable for a political European platform oriented at best practice guarantees for European citizens. Standardized methodologies were designed and tools developed to assess the quality of care of some selected health procedures.

The final result of the cardiovascular pilot involved a web-based tool that allows hospitals to confidentially self-benchmark their in-house mortality rate. After some preliminary discussions with DG SANCO, it seems that the tool developed by the cardiovascular pilot is of relevant interest for future projects, in particular for the project EURHOBOP (currently under negotiation with EAHC). The functions of the cardiovascular algorithm are now only available in the restricted area of the EUPHORIC website since they have to be considered a "beta" version and need to be validated. This activity will be carried out in future projects and EUPHORIC will carry out all the necessary bridging activities. In particular, cooperation with HOPE (European Hospitals and Healthcare Federation) will be established in order to disseminate the results in both networks.

The orthopaedic pilot enhanced the importance of having registers that are available to carry out outcome measurements especially in the field of arthroplasty. Therefore, it proposed to introduce two specific indicators related to arthroplasty in the indicators list: revision rate and revision burden. Moreover, it provided an assessment of the registers currently active in Europe and in other neighbouring countries. Based on a detailed analysis of the scientific literature, comparisons were made for some selected devices between the revision rates available from the published clinical studies and those published in the annual reports of different registers. All the relevant technical reports and related results will be made public only after approval by DG SANCO and DG Enterprise of both the adopted methodology and of the achieved results of the performed analyses.

The result of the activities carried out in WP 5.3 (risk adjustment pilot) was the description of different methodologies related to risk adjustment procedures and the steps to develop risk adjustment models. Direct standardization procedures using the entire population under study or the best performing hospitals (benchmark) as a reference were considered the best possible choices.

Routinely collected data, such as hospital discharge records, are an invaluable source of information, therefore, particular attention was paid to investigate their validity for all the areas concerned by the pilot. The limits of administrative databases were highlighted: although they clearly offer advantages in comparative evaluation of outcomes, being relatively inexpensive and generally covering a large population, they also have important drawbacks from a clinical perspective, that is a limitation of ICD coding and absence of many important clinical variables.

In conclusion, even if its interests were focussed on some selected procedures, EUPHORIC might be considered the initial spark to make policy makers and all the interested stakeholders aware that the implementation of systematic outcome assessment throughout all European member states might be possible and further investments should be sustained. In particular, EUPHORIC enhanced the important aspect that it is possible for hospitals to confidentially self-benchmark their in-house mortality rate when managing acute myocardial infarction, thereby triggering a process of improvement of provided health care with a direct benefit for the patients.

Dissemination should be considered a key action especially in the development of projects related to the public health field when not only scientists but also patients and citizens are

interested in the results achieved. To provide the most suitable information to all the targeted stakeholders, cooperation with people specialized in communication strategy should be considered. In cooperation with the scientific publisher Zadig, some specific documents that are useful in supporting the dissemination were produced (newsletter, brochure as well as leaflet and the short document "EUPHORIC at a glance" translated in all the eleven languages spoken in the participating countries, video, virtual table of discussion, press release). All these items will be downloadable from the project website after approval by the Commission. A model of the press release will be delivered to the Commission after approval of the report.

2. PROJECT SPECIFICATIONS

2.1 General objective of the project:

This multi-disciplinary project was oriented to policy authorities and policy makers and aimed at building a consortium of participating countries in order to:

- cooperate on benchmarking the outcomes of selected health performances
- exchange information on quality standards, best practice and effectiveness in public health, by developing and maintaining EU networks
- verify the hypothesis that the possibility of developing common outcome indicators in Europe exists
- identify common EU elements suitable for a political EU platform oriented at best practice guarantees for the EU citizens.

2.2 Specific objectives of the project

Specific aims of the proposed project were to:

- set up a high quality framework – consortium
- collect detailed information on health outcome indicators
- develop a standardized methodology
- assess quality of care of selected health procedures
- provide objective, transparent, high quality and standardized information that is easily accessible to users (doctors, health staff, health administration, decision makers, policy makers, EU people)
- provide assistance to EU countries for the development and implementation of a common monitoring system of standardized outcome indicators with a view to eventually creating common public health planning in Europe
- investigate validity of routinely collected data.

2.3 Work packages and deliverables

EUPHORIC was organized in 6 work packages linked to the specific objectives of the study as summarized in the following table where the most important deliverables that each work package has produced are listed.

Table 1. Summary of the specific objectives of the project, work packages, and deliverables

Specific objectives of the project	Work package(s)	Deliverables
Set up a high quality framework - consortium	WP 1 Management of the project	Useful communication within the project for both scientific and administrative tasks
	WP 3 Liaison with other EU projects, EU programmes and health stakeholders	Networking of the initial consortium with other groups
Collect detailed information on health outcome indicators	WP 4 Indicators development	Technical report based on a worldwide analysis of literature and existing health related websites
	WP 3 Liaison with other EU projects, EU programmes and health stakeholders	Compatibility of presented indicators and methods with ECHI
	WP 6 Setting up and maintaining an indicators database	Web-based database
Develop a standardized methodology	WP 5 Development of adverse-outcome risk indicators in real clinical and register databases, and their possible use in administrative systematic databases (pilot)	Pilots' technical reports
Assess quality of care of selected health procedures	WP 5 Development of adverse-outcome risk indicators in real clinical and register databases, and their possible use in administrative systematic databases (pilot)	Pilots' technical reports; Algorithm for hospital benchmarking
Provide objective, transparent, high quality and standardized information that is easily accessible to users (doctors, health staff, health administration, decision makers, policy makers, EU people)	WP 2 Dissemination strategy	Website (www. euphoric-project.eu), scientific and informative publications (brochure, the short document "EUPHORIC at a glance" and video), virtual table of discussion, final workshop
	WP 6 Setting up and maintaining indicators database	Web-based database
Provide assistance to EU countries for the development and implementation of a common monitoring system of standardized outcome indicators with a view to creating common public health planning in Europe	WP 2 Dissemination strategy	Website (www. euphoric-project.eu), scientific and informative publications (brochure, the short document "EUPHORIC at a glance" and video), virtual table of discussion, final workshop
	WP 5 Development of adverse-outcome risk indicator in real clinical and register databases, and its possible use in administrative systematic databases (pilot)	Technical reports
	WP 6 Setting up and maintaining indicators database	Web-based database
Investigate validity of routinely collected data	WP 5.3 Use of the available sources of information in participant countries in order to develop a standardized statistical methodology for comparative outcomes evaluation	Technical report

2.4 Time table and overview of the activities

The EUPHORIC project started at the end of 2004. The initial planned duration was 36 months. However, due to administrative problems, it was necessary to postpone the deadline of the project to the end of 2008. The relevant amendment was signed by the Commission on 26 January 2007. Therefore, the work plan was revised and all the deadlines were postponed for one year, taking into account the new deadline of the project.

Table 2 summarizes the time table of the six work packages.

Table 2. Work packages time table

WP	Title	Time table
1	Management of the project	Carried out during the whole duration of the project
2	Dissemination strategy	Carried out during the whole duration of the project
3	Liaison with other EU projects, EU programmes and health stakeholders	Carried out during the whole duration of the project
4	Indicators development	Started at the beginning of the project and finished in December 2007
5	Development of adverse outcome risk indicators in real clinical and register databases, and their possible use in administrative systematic databases	Started in 2007 and continued until the end of the project
6	Setting up and maintaining an indicators database	Started at the end of 2006 (setting up the website) and continued until the end of the project

Table 3 summarizes the "Activities/Tasks" undertaken in the project.

It must be kept in mind that the administrative problems that the project incurred during the first two years prevented the regular organization of the activities. Regarding the meetings, the original plan foresaw two meetings for each year of activity. In the first two years, the coordinators organized only two meetings because in that period the project had slowed down. However, since the deadline was postponed for one year, we can consider only one year of actual activity and, therefore, this task was completely achieved. Attention must be drawn to the fact that, despite the administrative problems incurred during the first period (2004-2006), which prevented the regular organization of the activities, the project was reorganized thanks to the concerted efforts made by the coordinator and the pilots' leaders. In fact, the third year (2007) signalled a period of intensive activity: cooperation among the partners was enhanced and the consortium was enlarged, the dissemination strategy was defined, connections with other EU projects were established, the results of the first phase – relevant to the selection and thorough description of the outcome indicators – were finalized. Furthermore, areas for pilot implementation were selected, pilot leaders were appointed, pilot protocols were finalized, and the web-based database of the selected outcome indicators was set up. During the fourth year (2008), the pilots were implemented and a strong boost was given to the dissemination activity. In the last two-year period, following DG SANCO's suggestions, it was possible to recover the time lost and be ready to achieve the foreseen objectives by the deadline.

After the appointment of both project leaders it became evident that the use of existing recent population-based registers to fit predictive functions of outcome after the selected procedures, and validation of these functions on routinely collected hospital discharge data, was more feasible as well as more efficient and effective than the originally proposed organization of the pilot based on active collection. Therefore, the main coordinator proposed that the amount initially allocated to perform the clinical monitoring be moved from theirs to the pilot leaders'

budget. Clinical monitoring is a very important activity when active data collection is organized, but not useful when routine data are used.

The pilots' leaders were requested to invest more resources than those planned in the contract in force in order to finance the requested additional duties. All the details were agreed upon with DG SANCO in order to be able to proceed with the project even without the official signature of the relevant amendment (3rd) that occurred after the end of the project (9 February 2009).

Table 3. Overview of the activities/tasks

WP	Activities/Tasks	Outcomes/ Deliverables	Date foreseen	Date of achievement	Level of achievement	Justification/ Problems encountered	Action to be taken to overcome the problem
1	Establishment of the initial network	Consortium	06/2006	12/2006	100%	Withdrawal of a partner	Inclusion of a new partner
	Contact between participants and DG SANCO	Communication	06/2006	02/2007	100%	Standstill of the project, change of the project leader	Definition of the 1st amendment
	Contacts among all the participants	Communication	06/2006	02/2007	100%	Standstill of the project, change of the project leader Moreover, partner GRI did not fulfil their duties. All the partners agreed in requesting their withdrawal	Definition of the 1st amendment A further amendment to the contract was requested
	Setting up the work plan	Work plan	03/2006	08/2007	100%	Reorganization of the project according to the suggestion received from DG SANCO	Meeting with DG SANCO officer (23/04/2007) Submission of the revised first interim report
	Organization of coordination meetings	Minutes	5 in total (2 each year)	16/12/2004 09/06/2006 24/04/2007 09/10/2007 27-28/03/2008	100%		
	Drawing up interim and final reports	1st financial and technical report	02/2007	02/2007 first submission 08/2007 submitted in revised form	100%	Reorganization of the project according to the suggestion received from DG SANCO	Meeting with DG SANCO officer (23/04/2007) Submission of the revised first interim report
		2nd financial and technical report	02/2008	03/2008	100%		
		Final financial and technical report	03/2009	05/2009	100%		
	Involvement of other countries (MS and non MS)	Official letters	06/2008	12/2007	100%		

Table 3. Overview of the activities/tasks *(continued)*

WP	Activities/Tasks	Outcomes/ Deliverables	Date foreseen	Date of achievement	Level of achievement	Justification/ Problems encountered	Action to be taken to overcome the problem
1	Evaluation of the project: preparation of the protocol	Document	12/2007	02/2008	100%	Not considered in the original project. Lack of a description of a detailed defined structure to build up the evaluation activity (WP organization, indicators, milestones). First time included in the template for reporting received from DG SANCO in June 2007	Organization in WPs. Definition of what to evaluate (meetings and project progress) to be implemented only during the last year of activity
	Evaluation of the project: administration of the questionnaire	Report	12/2008	02/2009	100%	Problems in collecting the questionnaires duly filled in by the partners	Sending reminder mail
2	Define the diffusion policy	Document	06/2007	04/2007 in draft form 10/07 in final form	100%	Approval of the document by all the partners during the Helsinki meeting (09/10/2007)	
	Preparation of the dissemination plan	Document	12/2007	11/2007 in draft form 02/2008 in final form 02/2009 updated in order to include all the involved institutions	100%	Collection of the information from the partners	Sending reminder mail
	Setting up of a website	Website (beta version)	04/2007	04/2007	100%		
		Final version	10/2007	10/2007	100%		
		Updating according to the additional requirements	12/2008	12/2008	100%		
	Preparation of the final workshop	Workshop	10/2008	12/2008	100%	Unavailability of the conference room at the ISS for the initially planned date	

Table 3. Overview of the activities /tasks *(continued)*

WP	Activities/Tasks	Outcomes/ Deliverables	Date foreseen	Date of achievement	Level of achievement	Justification/ Problems encountered	Action to be taken to overcome the problem
3	Setting up contacts with other projects	Sharing of methodologies and results	12/2007	10/2007	100%		
4	Defining a list of outcome indicators	List of indicators	06/2006	06/2006	100%		
	Assessing the current situation in participating countries	Deliverable	06/2006	04/2007	100%	Standstill of the project, change of the project leader	Definition of the amendment (26/1/2007)
	Select diseases and procedures to test some indicators (pilot)	Technical presentation	06/2006	04/2007	100%	Standstill of the project, change of the project leader, appointment of pilot leaders	Definition of the amendment (26/1/2007)
5	WP 5.1 Cardiovascular pilot: protocol definition risk adjustment methods	Document	07/2007	07/2007 draft version 09/2007 final version	100%	Definition of the databases to be included and of the protocols allowing sharing of data among partners. Inclusion of new collaborating partners	The protocol was defined in its draft form on July 2007 and presented to all the partners in its final form on October 2007
	WP 5.1 Cardiovascular pilot: indicators testing	Report	09/2008	02/2009	100%	Delay in the completion of the statistical analysis. Contemporary implementation on the website of the hospital benchmarking algorithm (not originally foreseen)	
	WP 5.2 Orthopaedic pilot: protocol definition	Document	07/2007	09/2007	100%	Definition of the contribution of each partner. Inclusion of new collaborating partners	The protocol was defined in its draft form on July 2007 and presented to all the partners in its final form in October 2007
	WP 5.2 Orthopaedic pilot: protocol realization	Report	09/2008	04/2009	100%		

Table 3. Overview of the activities/tasks *(continued)*

WP	Activities/Tasks	Outcomes/ Deliverables	Date foreseen	Date of achievement	Level of achievement	Justification/ Problems encountered	Action to be taken to overcome the problem
5	WP 5.3 Description of the hospital discharge record datasets	Report	12/2007	01/2009	100%	Avoiding duplication with the information requested by the cardiovascular questionnaire	Inclusion of all the information in a single questionnaire (decision adopted during the Helsinki) meeting 09/10/2007). Definition of additional WP 5.3. Cooperation with HDP2 Project
	WP 5.3 Test of a standardized methodology for the calculation of CV and orthopaedic selected indicators	Reports	12/2008	01/2009	100%		
6	Setting up the web-based DB	Database	06/2007	06/2007	100%		
	Database input	Database available online	10/2007	10/2007	100%	Database is available online in the members' area	
	Database updating	Database updated	12/2008	12/2008	100%	Missing information in some countries. Inclusion of additional information	Participants requested to integrate the existing information

3. TECHNICAL IMPLEMENTATION OF THE PROJECT

3.1 Activities related to horizontal work packages

WP 1 Management of the project

In this work package, the following actions were undertaken by the project management:

- establish a network among the partners and other European institutions involved in outcome research and outcome assessment.
- act as the contact between all the participants and DG SANCO
- assure good communication and cooperation among all participants
- set up the work plan of the project and assure that the described objectives are attained
- organize coordination meetings
- draw up the interim and final reports
- involve the highest number of MS
- evaluate the project.

EUPHORIC started on 15 December 2004. From the beginning it suffered from a series of organizational difficulties that prevented its regular development and required the reorganization of the project: partner HFA withdrew in March 2005; the previous project leader resigned in April 2006; and in November 2007, the EUPHORIC consortium agreed with DG SANCO to ask for the withdrawal of partner GRI who, during 2007, did not fulfil their duties in contributing to the reorganization of the project. The amendment related to the formalization of the first two changes (substitution of the partner and appointment of the new project leader) was defined on 26 January 2007. The same document led to the deadline of the project being postponed to 14 December 2008. Consequently, in agreement with DG SANCO officers' suggestions, the consortium worked very hard to redesign the project in order to start the pilot phase and achieve the foreseen objectives respecting the new work plan. GRI officially withdrew from the project on 6 February 2008. According to the indications received from the Commission, the whole GRI budget was redistributed in the project. Due to the very difficult situation created by GRI, the procedure relevant to the finalization of the amendment took a long time. The amendment was eventually signed on 9 February 2009. Moreover, the recovery of the GRI pre-financing payment by the main beneficiary is still ongoing and due to several refusals by GRI official legal action will be needed.

The reorganization of the project mainly concerned two issues: the greater authority given to the pilots and, as a consequence, to the partners appointed as pilot leaders who were requested to invest more manpower than that foreseen in the contract, and the inclusion of additional WPs to fill in the gap left by partner GRI. The pilots were based on the use of existing recent population-based registers to fit predictive functions, and testing some selected indicators on routinely collected hospital discharge data instead of organizing active data collection. The additional WPs gave the project added value by offering the opportunity to include the achievement of supplementary objectives not originally considered in the proposal. Some of these activities were related to the improvement of the dissemination. To achieve this objective, in April 2008, the main beneficiary started cooperating with Zadig, an Italian scientific publisher.

Activities undertaken

The strengthening of the institutions involved in the project is a vital task in carrying out a project. Therefore, in the first two years of activity of the project, most of the tasks were aimed at building up a consortium capable of fulfilling the objectives of the project. Since there had not been any previous collaboration among the partners, the first step was to introduce the participating institutions and all the partners were invited to present themselves by describing their country (political-demographical situation, health care systems) and their institution both during the first meeting and in a more detailed way during the survey. They were also asked to give details about the projects related to outcome research that they were carrying out and to describe their potential contribution to EUPHORIC. All the information was collected in the first deliverable "Survey: the first phase of the project" (Deliverable n. 1) and further uploaded onto the project website.

During the second phase of the project, after appointing the new project leader, contacts among partners were intensified by sending out regular updates on the achievements of the project and by exchanging information, comments and suggestions via e-mail and organizing coordination meetings. An intranet platform on the project website was implemented in order to facilitate communication and exchange documents among the partners. To fulfil the stated objectives, and to respect the project's new organization, a management structure was defined considering both a core working group (coordinator and pilot leaders) and specific working groups for each pilot. The whole project was organized in WPs and the main deliverables were detailed and included each partner's specific tasks. The work plan was reorganized according to the new deadline (14 December 2008). The new structure of the project was described in the first interim report submitted in August 2007.

The main beneficiary also acted as a contact between the participants and DG SANCO, both for administrative and technical issues, by forwarding information/requests received by the HSWP and by forwarding the partners' comments to the HSWP (as an example see the participation in the preparation of the HSWP glossary [section Benchmarking - Best practices, Deliverable n. 2] and submission of some proposals to the Network of Working Party Leaders for future SANCO actions in the health information and knowledge domain). The project coordinator regularly sent the HSWP secretariat the requested progress reports. It also participated in the following meetings of the Health System Working Party (HSWP): 4th on 26 April 2005 when it presented the project, 7th on 5 December 2006, 8th on 11-12 June 2007, 9th on 19-20 November 2007, 10th on 15-16 July 2008, and 11th on 20-21 November 2008. The IMAS-IMIM partner (cardiovascular pilot leader) participated in the 8th, 10th and 11th HSWP meetings. During the 4th coordination meeting (Helsinki, October 2008), the project leader invited all the partners to register on the HSWP website in order to be updated about the HSWP activities.

Meetings organization

As foreseen in the contract, five project coordination meetings and a final workshop were organized during the whole project. Moreover, in order to decide on some specific issues related to the organization of the three pilots (cardiovascular, orthopaedic, risk adjustment and statistics), nine specific technical meetings were arranged. In order to solve particular administrative and technical problems, it was agreed with DG SANCO's officers to have two coordination meetings.

Project coordination meetings

All the information (agenda, minutes of meeting, presentations) is available on the website (see Section: Previous events http://www.euphoric-project.eu/?q=node/63).

1st Project coordination meeting – 16 December 2004, Rome

On 16 December 2004, during the workshop "TOWARDS A NEW HEALTH CARE SYSTEM" organized by the main beneficiary (ISS - Istituto Superiore di Sanità), the EUPHORIC project was officially presented to the Italian scientific community together with the results of the national projects related to outcome research led by ISS and funded by the Italian Ministry of Health in 2002. All the associated beneficiaries were invited to participate at a round table to present themselves and their contribution to EUPHORIC. The presentations are available on the EUPHORIC project website.

At the end of the workshop the main beneficiary organized a coordination meeting to present the structure and the work plan of the project and to discuss the organization of the first phase (survey) to all the partners.

2nd Project coordination meeting – 9 June 2006, Rome

The second coordination meeting was held in Rome at the Istituto Superiore di Sanità on 9 June 2006. All the associated beneficiaries and collaborating partners, included at that time, participated in the meeting. EFORT-EAR replaced HFA (Austrian Heart Foundation) as partner who had withdrawn from the project in spring 2005. It was allowed to participate in the meeting since its inclusion in the project had been accepted by the Commission, although the amendment would be officially signed in January 2007.

During the meeting, EFORT-EAR was put in charge of the orthopaedic pilot (WP 5.2) to be carried out during the second phase of the project. Moreover, the technological partner (CASPUR) involved in the setting up of the website was presented.

3rd Project coordination meeting, Luxembourg, 24 April 2007 (DG SANCO)

Participants: All the partners (Absentees: AB DEASL, AB GRI, CP NCHP), DG SANCO (M. Artur Furtado). The meeting was held at HITEC Building (DG SANCO Luxembourg). The aim of the meeting was to involve all the partners in the pilot phase, define WPs, tasks and deliverables.

4th Project coordination meeting, Helsinki, 9 October 2007 (STAKES)

Participants: All the partners (Absentees: AB GRI, CP CAHTA, CP NCHP). The meeting was hosted by STAKES. The aims of the meeting were the presentation of both pilots' protocols, the introduction of new collaborating partners (BQS, LBI-HTA, SAR, SOFCOT, TILAK) and the planning of the activities of the following semester. Representatives of ECHIM, OECD and HDP participated in the meeting. Partner IMAS-IMIM supported the project leader in the preparation of the minutes.

5th Project coordination meeting, Innsbruck, 27-28 March 2008 (EAR)

Participants: All the partners (Absentees: CP BQS, CP CAHTA, CP NCHP, CP TILAK, CP SOFCOT, CP SAR). The meeting was hosted by EAR. The aims of the meeting were the presentation of the cardiovascular and orthopaedic pilots' first results, the presentation of the working plan of the risk adjustment and statistics pilot, the introduction of the new collaborating partner ISPHA and the planning of the activities of the following semester. Partner EAR supported the project leader in the preparation of the minutes.

Final Workshop, Rome, 11-12 December 2008 (ISS)

All the information (programme, introductory poster, summary of the workshop, presentations) is available on the website (see Section: Final workshop http://www.euphoric-project.eu/?q=node/397).

Participants: All the partners (AB NKUA, CP BQS, CP NCHP, CP SOFCOT could not participate) and some invited speakers from other projects closely connected to the development of indicators and, therefore, to EUPHORIC (OECD, ECHIM, HDP). The workshop was hosted by ISS. The aims of the meeting were the presentation of the final results of the project and the discussion about the implementation of a dissemination strategy. In close cooperation with Zadig, the project coordinator prepared a summary of the results of the workshop that was uploaded onto the website. A special issue of the EUPHORIC newsletter (N.5) about the workshop results was circulated among all the subscribers to the EUPHORIC newsletter (more than 100 people).

Specific technical meetings

All the information (agenda, minutes of meeting, presentations) is available on the website (see Section: Previous events http://www.euphoric-project.eu/?q=node/63).

Joint meeting EAR-EUPHORIC, Barcelona, 15-16 January 2007 (CAHTA)

Participants: Project leader, orthopaedic pilot coordinator (EAR), partner IMAS-IMIM, partner CAHTA. The meeting was hosted by CAHTA. It was organized so as to share with CAHTA the experience in setting up arthroplasty registers (15 January 2007) and was aimed at establishing cooperation in the orthopaedic pilot and possible cooperation between EUPHORIC and partner IMAS-IMIM (16 January 2007). After this meeting, CAHTA asked to be included in the project as collaborating partner.

Core group project meeting, Barcelona, 11 April 2007 (IMAS-IMIM)

Participants: Project and pilots' leaders. The meeting was hosted by IMAS-IMIM. The aims of the meeting were: 1) to officially put partner EFORT-EAR (after their inclusion in the project) and partner IMAS-IMIM in charge of the orthopaedic and cardiovascular pilots; 2) to define the organization of the pilot phase.

Core group project meeting, Barcelona, 4-5 July 2007 (IMAS-IMIM)

Participants: Project leaders and the pilots' leaders. The meeting was hosted by IMAS-IMIM. Aims of the meeting: to finalize the pilots' protocols, to discuss the detailed WPs and work plan organization in order to have a general overview about the partners' participation, and to do some fine tuning in the overlapping regions of both pilots. Partner IMAS-IMIM supported the project leader in the preparation of the minutes.

Working group on statistics meeting: Helsinki, 8 October 2007 (STAKES)

Participants: ISS, EAR, IMAS-IMIM, NKUA, STAKES. The meeting was hosted by STAKES. The aim of the meeting was the definition of an additional WP about risk adjustment and statistical analyses (WP 5.3), transversal to both pilots. Partner IMAS-IMIM supported the project leader in the preparation of the minutes.

Project work-in progress meeting: Athens, 4 December 2007 (NKUA)

Participants: Project leader, pilots' coordinators, NKUA partner. The meeting was hosted by NKUA. The aim of the meeting was to plan the detailed contribution of partner NKUA to the WP on statistics and risk adjustment.

Orthopaedic pilot coordination meeting: Stockolm, 31 January 2008 (KI)

Participants: ISS, EAR, STAKES, KI. The meeting was hosted by KI. The aim of the meeting was to define the activities to be carried out by KI and STAKES for the orthopaedic pilot concerning the assessment of the outcome measurement system based on outcome registers in Sweden and Finland and the public health medical device failure reporting system. Agreement on the DEASL leadership of WP 5.3. Partner EAR prepared the minutes.

Working group on statistics meeting: Innsbruck, 26 March 2008 (EAR)

Participants: ISS, EAR, IMAS-IMIM, NKUA, STAKES, KI, DEASL. The meeting was hosted by EAR. The aim of the meeting was to discuss the protocol of WP 5.3 (Risk adjustment and statistical analyses) led by Danilo Fusco (partner DEASL). Partner EAR supported the project leader in the preparation of the minutes.

Orthopaedic pilot coordination meeting: Helsinki, 16 June 2008 (STAKES)

Participants: EAR, STAKES, KI. The meeting was hosted by STAKES. The aim of the meeting was to focus on the progress of the activities related to the assessment of the outcome measurement system based on outcome registers in Sweden and Finland and the public health medical device failure reporting system. Partner EAR prepared the minutes.

Orthopaedic pilot coordination meeting: Stockolm, 10 September 2008 (KI)

Participants: EAR, STAKES, KI. The meeting was hosted by KI. The aim of the meeting was to focus on the preparation of the final report about the assessment of the outcome measurement system based on outcome registers in Sweden and Finland and the public health medical device failure reporting system. Partner EAR prepared the minutes.

Coordination meetings with DG SANCO

1) 23 April 2007 - Luxembourg

The project leader and the pilots' leaders met M. Artur Furtado on 23 April 2007 in order to discuss the new organization of the project following the amendment signed by the Commission on 26 January 2007. This meeting eventually solved some administrative issues that had prevented the regular progress of the project, such as the substitution of HFA with EFORT-EAR and the change of the project leader. The EUPHORIC project was originally structured in three phases: survey, pilot and dissemination. The proposed organization of the pilot was based on active collection of data and the use of existing databases. However, on the basis of the results obtained during the survey phase (Deliverable n. 1 submitted to DG SANCO in its final form in June 2007), it appeared that the use of existing recent population-based registers to fit predictive functions of outcome after the selected procedures, and testing these functions on routinely collected hospital discharge data was feasible and more efficient and effective for the project's purpose. Moreover, the outputs produced could be more easily implemented in the routine health information flow systems. Therefore, it was proposed that both pilots would use only these types of data. Dr. Gerold Labek (partner EAR-EFORT, Austria) and Prof. Jaume Marrugat (partner IMAS-IMIM, Spain) were appointed as leaders of the orthopaedic and the cardiovascular pilots respectively. It was agreed that special efforts would be made to enlarge the consortium by including as many countries and databases as possible. According to this new organization and in order to respect the new work plan and achieve the stated objectives, partners IMAS-IMIM and EAR-EFORT were requested to immediately invest more manpower than that foreseen in the contract, without waiting for the signing of the amendment.

2) 20 November 2007 – Luxembourg

The project leader met the officers of DG SANCO Unit C1 (M. Jean Luc Sion and M. Dimitri Agneskis) and Unit C2 (M. Artur Furtado) in order to discuss how to proceed regarding the changes in the main coordinator and pilot coordinator budgets, as well as request the

withdrawal of partner GRI who did not fulfil their duties (see below). It was agreed to prepare a single amendment to the contract including both issues. The formalization procedure of the amendment regarding this issue was concluded on 9 February 2009.

Drawing up of the interim and final reports

Based on the contributions received by all the partners, the project coordinator prepared both the technical and financial interim and final reports.

The first interim report, referring to the period 15 December 2004 - 14 December 2006, was submitted on 16 March 2007. It was then revised according to the new template received by the Commission and included DG SANCO's suggestions. It was submitted in its final form on 9 August 2007.

The second interim report, referring to the period 15 December 2006 - 14 December 2007, was sent to the Commission on 15 March 2008.

The project coordinator set up a subcontract with the company united languages sas for the linguistic revision of reports, documents and deliverables, prepared by the coordinator and submitted to the Commission and for all the texts uploaded onto the website. Each pilot leader took care of the linguistic and editing revision of the reports related to each pilot.

Inclusion of collaborating partners

Regarding the original network composition, the following institutions were included in the project as collaborating partners:

- Catalan Health Technology Assessment and Research, Spain (27/03/2007)
- Slovak Arthroplasty Register (Slovak Republic) (18/7/2007)
- Ludwig Boltzmann Institut for Health Technology Assessment (Austria) (17/10/2007)
- Arthroplasty Register Tyrol (Austria) (17/10/2007)
- French Society of Orthopaedic and Trauma Surgery (France) (17/10/2007)
- BQS Bundesgeschäftsstelle Qualitätssicherung GmbH (Germany) (21/12/2007)
- Israel Society for the Prevention of Heart Attacks at Neufeld Cardiac Research Institute (Israel) (21/12/2007).

The new collaborating partners contributed to the project by either providing useful data from their own databases or supporting the dissemination of the results and the connection with other projects regarding the same topics.

In particular, the Israel Society for the Prevention of Heart Attacks at the Neufeld Cardiac Research Institute contributed to the further development of the cardiovascular pilot study by supplying the EUPHORIC cardiovascular database with the ACSIS database 2004 and 2006 from Israel. Moreover, cooperation with this institution facilitated the inclusion on the same database of the Euro Heart Surveys 2000 and 2005 on Acute Coronary Syndrome from the European Society of Cardiology (see WP 5.1).

The other collaborating partners closely cooperated with the orthopaedic pilot. Best practice strategies for the work with data collections and registers, definition of criteria for data collections to be used in health technology assessment and other disciplines, and transferring these to requirements for data collections were identified as topics of shared interest with LBI HTA (see WP 5.2, Deliverable n. 9.5).

Cooperation with ECHIM

During 2007, EUPHORIC cooperated with the ECHIM project by proposing some outcome indicators to be considered for the short list (see WP 3 Liaison with other projects).

Within the framework of updating the ECHI short list, on 2 October 2007, the project leader was invited by Prof. Pieter Kramers (ECHI project coordinator) to compare the short list and the

EUPHORIC indicator list in order to suggest a maximum of five EUPHORIC indicators to be included on the ECHI short list. A thorough analysis of the ECHI short list and of the indicators included in the ICHI (International Compendium of Health Indicators) was carried out in cooperation with both pilots' leaders (EAR-EFORT, IMAS-IMIM). The following four indicators were selected as possible candidates: AMI case fatality rate; fatality rate after CABG; revision rate (orthopaedic); and revision burden rate (orthopaedic).

The description of the indicators was prepared according to the ECHI requests and submitted in order to be discussed during the Working Party on health indicators held in December 2007 (Deliverable n. 4). The definition of the AMI 30-day in-hospital case fatality rate indicator given by EUPHORIC was included in the documentation sheets for the ECHI short list indicators (www.echim.org/docs/documentation_sheets.pdf) and in the ECHIM final report (www.echim.org/docs/ECHIM_final_report.pdf).

Evaluation plan

Following the suggestions received by DG SANCO officers when the first interim report was submitted, a protocol for the evaluation of the project was set up (Deliverable n. 3). It must be stated that the initial project neither foresaw an organization in WPs nor a detailed definition of the activities and of the related indicators to monitor their progress. It is evident that, in this situation, this kind of tool's usefulness is limited and its application was restricted to the last year of activity. Therefore, it was decided to focus the development of the evaluation plan on two aspects: 1. Active participation of both associated and collaborating countries in the project activities; 2. Respect of scheduled milestones and deliverables according to the project WPs. The meetings were a key event for establishing good relationships among the partners and so it was decided to collect information about their participation, suggestions and feedback by means of an *ad hoc* developed questionnaire that was filled in by all the partners after the final workshop held in Rome on 11-12 December 2008. A description of the analyses of the collected data was included in the Deliverable n. 3. In order to evaluate the second aspect, a set of indicators was defined. Measurements were taken after the final workshop.

Problems encountered

As described in the introduction, several problems arose at the beginning and continued during the whole project, thus preventing its regular development.

First of all, the withdrawal of the associated partner, Austrian Heart Foundation (HFA), from the project in spring 2005. The main beneficiary (ISS) was forced to replace it with an another partner in order to maintain the EU contribution.

Secondly Fulvia Seccareccia resigned as project leader (communication of 10 April, 2006).

Unfortunately, formalizing all these changes took a long time and the related amendment was agreed upon by the European Commission in December 2006 and received by the main beneficiary duly signed in February 2007. Owing to these inconveniences the project came to a standstill and consequently there was a deferral in the milestones envisaged in the initial work plan. For this reason the deadline of the project was postponed by one year and the overall schedule was reorganized. Also, the pre-financing payment was delayed and the beneficiaries (who first had signed the Grant) only received it in June 2006.

The other important issue concerned partner GRI who did not fulfil their duties. On the basis of their expertise, partner GRI initially proposed to contribute to the EUPHORIC project by establishing cooperation with Eurocare. Therefore, at the beginning of April 2007, they were given the responsibility, together with partner STAKES, of leading the WP 3 "Liaisons with other EU projects". They promised also to prepare a proposal for possible cooperation with other EU projects related to transplantation. This document was never submitted by GRI to the coordinator. Even though the coordinator highlighted the importance of the Luxembourg

meeting (3rd Project coordination meeting, 24 April 2007) for the whole organization of the project and stressed partners' participation, partner GRI did not attend. Similarly, they did not attend the Helsinki meeting (4th Project coordination meeting 8-9 October 2007) that was also a crucial event for the development of the project (in fact both pilots' leaders were requested to describe in detail the organization of each pilot and to organize the contribution of each partner) nor even informed of the reasons for their absence. Furthermore, despite several invitations and reminders made by the project leader, they refused to submit their contribution to the first interim report revised according to the requests of the Commission. As a consequence, they were excluded from the report. Finally, the issue regarding GRI, whose further participation was a hindrance to the regular development of the activities, led to an amendment being requested which made the situation even more difficult because GRI did not respond to the requests made by the Commission. The question started at the end of May 2007 and even if a letter of withdrawal was sent by GRI on 6 February 2008 and the related Grant Amendment was signed on 9 February 2009, all the financial aspects have not ended yet and will probably require the main beneficiary to take legal action.

How problems were resolved

At the end of 2005, a new partner, EFORT-EAR, with all the requirements defined in the Grant Agreement, was selected as a new associated beneficiary by ISS. EAR (European Arthroplasty Register) is a project within EFORT (European Federation of National Associations of Orthopaedics and Traumatology).

In April 2006, a request for an amendment to the Grant Agreement was sent to the European Commission by the main beneficiary, including:

- the formalization of EFORT-EAR as associated beneficiary
- the request for the extension of the project's duration for another year (new deadline 14 December 2008)
- the replacement of Fulvia Seccareccia with Marina Torre as project leader.

In June 2006, the advance payment was delivered to those partners already included in the contract.

During the Helsinki meeting (8-9 October 2007), all the participating partners agreed to request the exclusion of partner GRI from the consortium and make a proposal describing additional WPs which were relevant to both pilots and could be funded using the residual GRI budget. The technical proposal was discussed with M. Furtado who approved it.

This decision was made because the introduction of another associated beneficiary into the current work plan was difficult (both because most of the activities had already started and because the administrative procedures to substitute a partner with another would need some time) and that the remaining time frame would make it very difficult for any institution to perform a work package designed for a 3-year period within several months.

Partner GRI withdrew from the project on 6 February 2008. Since the technical and financial report submitted by GRI describing the activities carried out during the first phase of the project did not fulfil the requirements stated by the Commission, the main beneficiary was asked by the Commission to recover the advance payment from GRI and to reinvest it in activities related to the dissemination of the results that would give added value to the project (see WP 2).

WP 2 Dissemination strategy

Dissemination plan available: ☐ no ☒ yes

Dissemination is a key action in a project. The aim of this WP was to define the diffusion policy and to carry out the dissemination of the results.

The EUPHORIC dissemination strategy is thoroughly described in the dissemination plan (Deliverable n. 5). It includes the description of the dissemination policy that was proposed by partner IMAS-IMIM and approved by all the partners during the 4th Project coordination meeting (Helsinki, 2007). All the partners were asked to consider the dissemination of the EUPHORIC results in their own networks (public health, scientific societies, universities) also taking into consideration the collection of feedback (comments, suggestions) that came from the addressees.

Following the withdrawal of partner GRI, the project coordinator agreed with the EU Commission to reinvest the recovered budget in activities related to the dissemination. Therefore, in April 2008, it started cooperating with the scientific publisher Zadig who facilitated communication between EUPHORIC scientific partners and the partners' external relations office by:

- setting up strategies to communicate EUPHORIC contents and results to stakeholders and the general public
- the participation in local events and workshops for stakeholders
- the design and implementation of a section devoted to internal communication between Research Lines (RL) (community tool) and a section to outreach, to publish news, reports, editorial material, and a newsletter on the official EUPHORIC website. Special care was devoted to link EUPHORIC's main website to each individual website developed within different RLs
- exploiting the website as a communication tool by producing different tools: publication of editorial products and reports designed for different stakeholders
- promoting the project through printed journals and magazines.

Zadig (http://www.zadig.it/) is a journalistic and publishing company dealing with the definition and implementation of communication strategies on specialized subjects. It mainly focuses on topics related to medicine and health, environment, energy, science, school and human development. Generally, it makes use of its journalistic and publishing experience in all those situations where the ability to communicate is required.

Dissemination of the results was carried out by cooperating with the Health System Working Party (HSWP), the Working Party on Health Indicators and other European health projects. MS health authorities network, scientific societies, stakeholders, and the academic world were involved in achieving this objective.

Most of the dissemination activities were related to making the results available both as scientific and informative publications for policy makers, stakeholders and citizens.

Dissemination activities had great importance especially in the months after the end of the project (14 December 2008). Since that time, all the results have been finalized and available, therefore, the project coordinator agreed with the partners to continue even after the submission of the final report and to cooperate with Zadig at least until the submission of the final report.

Activities undertaken

The first release of the dissemination plan, approved by all the partners during the 4th Project coordination meeting (Helsinki, 2007) and submitted to the Commission together with the 2nd

interim report, was implemented and improved thanks to the cooperation with Zadig that gave an important boost to the dissemination activities. Besides the preparation of specific technical reports and presentations in conferences targeting the scientific community, a set of products targeted at a wider public (including the academia, policy makers, stakeholders, public health institutions and other European projects) was defined. The aim of these activities was to provide the partners with materials that were also useful for local dissemination in the participating countries and to specifically target patients. In order to enlarge the network for the dissemination, useful contacts were established by partner STAKES with OECD and ECHIM projects and by the project coordinator with the European Patients' Forum and other projects related to EUPHORIC (see WP 3). Moreover, all the partners were requested to circulate the EUPHORIC products within their institutional dissemination networks also taking into consideration the collection of feedback (comments, suggestions) received from the addressees.

Dissemination was based on the following activities:

- identification of the project
- design of a website and selection of the technological partner
- design and publication of the information leaflet
- publication of the newsletter
- preparation of selected documents requested by DG SANCO
- organization of the final workshop
- preparation of a brochure
- preparation of an the short document "EUPHORIC at a glance"
- preparation of a video
- organization of a virtual table of discussion
- preparation of a press kit.

Identification of the project

To characterize the project while disseminating the results, a logo (Annex 1) was designed to be used in all of the publications related to EUPHORIC (website, publications, reports, presentations). The logo represents a faun. In Greek mythology the faun participated in the Dionysus procession expressing euphoric gaiety. The logo was presented to all the partners during the 2nd coordination meeting.

Design of a website and selection of the technological partner

The main tool supporting the dissemination of the results has been the project website (www.euphoric-project.eu). The EUPHORIC website is both an output of the project and the means by which most of the results have been and will be disseminated to the international audience. The website contains special pages with contributions from each WP. A password protected access to the website enables only the EUPHORIC participating countries to contribute to the development of the website and enter the relevant information while, on the other hand, public access to the web guarantees the dissemination of the information to both the scientific audience and the public. The website was publicized by the partnership organizations and links to the website were made available from other appropriate websites.

The website was periodically updated and linked to the EU official website in order to make the results available to EU authorities, institutions, study participants and citizens. Moreover, it was achieved by following the W3C accessibility guidelines and the usability rules. Information was put online as it became available instead of waiting until the end of the project. All the disseminated documentation, information or material are free of charge and accessible by internet.

In September 2006, the Inter-University Consortium for the Application of Super-Computing for Universities and Research (CASPUR www.caspur.it), selected by the main beneficiary as

technological partner, started up the design and construction of the EUPHORIC website. CASPUR's role in the EUPHORIC project was 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 website is housed at CASPUR and is reachable at www.euphoric-project.eu. The website also hosts the web-based database of the selected outcome indicators (see WP 6) and, in the members area, the benchmarking algorithm developed in the cardiovascular pilot (see WP 5.1). In order to allow the more complete dissemination of the results, even if the project formally ended on 14 December 2008, CASPUR will continue carrying out the housing and maintenance of the EUPHORIC site during the first months of 2009.

Design and publication of the information leaflet

In November 2006, project leaflet was designed. The leaflet, approved by all the partners, was translated into the 11 languages spoken in the countries of all the partners participating in the project and is downloadable from the website homepage.

Publication of the newsletter

During the 4th Project coordination meeting held in Helsinki (October 2007), all the partners agreed to consider preparing an electronic bulletin (newsletter) as an additional instrument to support the dissemination.

The newsletter was implemented as part of the collaboration with Zadig. Since June 2008, five newsletters have been published and one is planned after the approval of the final report. All the published newsletters are available on the website (http://www.euphoric-project.eu/?q=taxonomy/term/3). The newsletter summarizes the data presented on the website and is sent by e-mail to selected institutions in the participating and non-participating EU countries. It is disseminated to more than 100 subscribers and to the networks of the EUPHORIC members. In Italy, each newsletter is also launched on the Italian website "Epicentro" (www.epicentro.it), the portal set up by the National Centre of Epidemiology at the ISS. Epicentro is a web-based tool aimed at improving access to epidemiological information for all public health workers. It accounts for more than 130,000 visitors monthly and now also gives special focus to EUPHORIC (http://www.epicentro.iss.it/focus/euphoric/euphoric.asp).

The following issues have been published:

- Newsletter N.1, Year 2008, 27/06/2008
- Newsletter N.2, Year 2008, 28/07/2008
- Newsletter N.3, Year 2008, 05/11/2008
- Newsletter N.4, Year 2008, 05/12/2008
- Newsletter N.5, Year 2009, 29/01/2009
- Newsletter N.6, Year 2009, published after approval of the final report.

Preparation of selected documents requested by DG SANCO

In June 2008, the project leader, in cooperation with the pilot leaders, prepared the fact sheet requested by the Directorate-General for Health and Consumers of the European Commission to be included in the portfolio booklet on the projects funded under the First Public Health Programme (2003-2007) in 2003 and 2004.

In summer 2008, the project leader, in cooperation with Zadig, developed a summary web page for DG SANCO's website with the main objectives, methodology, results, overall and by case study of EUPHORIC.

Organization of the final workshop

The final workshop of the project was held in Rome at the ISS on 11-12 December 2008. During the workshop, the results of the project were presented by both the associated

beneficiaries and the collaborating partners. Prof. Björn Smedby (HDP2 Project) and Dr. Sandra Garcia Armesto (OECD, HCQI project) were invited. All the information (programme, introductory poster, summary of the workshop, presentations) is available on the website (see Section: Final workshop http://www.euphoric-project.eu/?q=node/397).

Preparation of a brochure

In cooperation with Zadig, the project leader set up a brochure describing the project and the results achieved. The contents of the brochure, aimed at providing information to the policy makers and the health stakeholders, were shared and agreed with DG SANCO. The brochure was translated in all the languages spoken in the project (see the attached press kit). After approval by the Commission, it will be downloadable from the project website. Partner DEASL was involved in the scientific contents revision and all the partners in the final linguistic revision.

Preparation of the short document "EUPHORIC at a glance"

In cooperation with Zadig, the project leader set up the short document "EUPHORIC at a glance" giving a technical overview of the project and its results. The contents of the short document aimed at providing information to specialists interested in the field of health outcome research, were shared and agreed upon with DG SANCO. The short document "EUPHORIC at a glance" was translated in all the languages spoken in the project. After approval by the Commission it will be downloadable from the project website. All the partners were involved in the final linguistic revision.

Preparation of a video

During the 10th meeting of the Health System Working Party, held in Luxembourg on 15-16 July 2008, the EU project officer, Artur Furtado, asked the EUPHORIC project leader to prepare a video related to the subject of outcome indicators and to the topics developed in the project. This item was included in the objectives of the additional subcontract signed with Zadig and funded with the budget recovered from the withdrawal of partner GRI. The video is included in the attached press kit and will be uploaded onto the project website after the approval by the Commission. Interviews with the project leader (Marina Torre, ISS), the cardiovascular pilot leader (Jaume Marrugat, IMAS-IMIM), the orthopaedic pilot leader (Gerold Labek, EAR), the person in charge of the WP 3 "Liaisons with other projects" (Unto Häkkinen, STAKES) and the ECHIM project leader (Arpo Aromaa) were included on the video.

Organization of a virtual table of discussion

In November 2008, together with the Commission, it was agreed that also the patients' point of view about the possible improvement in provided health care that comes from the results of projects like EUPHORIC, should be taken into consideration as it might give added value to the overall results of the project. Therefore, after the end of the project in February 2009, Zadig in cooperation with the project leader, set up a virtual table of discussion extended to include the main patient associations and possibly European citizens so as to share the rationale and the objectives of the outcome indicators. Interviews were first done with epidemiologists that are an important reference at an international level. The aim was to present different opinions about the publication of the data resulting from the use of the outcome indicators (for example, in benchmarking hospitals).

Furthermore, some European networks that are interested in the EUPHORIC results and possible further developments were involved in the discussion, especially in connection to patient associations. Starting from these first contributions, the discussion was launched by asking for the participation of other interlocutors: patient associations and citizens, policy makers, etc.

The table is still open at the moment of the submission of the present report. The results will be summarized in a short report that will be sent to the Commission and made downloadable from the website when approved.

Preparation of a press kit

The brochure, the short document “EUPHORIC at a glance”, the video and a press release were included in a press kit.

Publications

All the technical reports and deliverables submitted to the Commission and attached to the interim reports are downloadable from the project website (http://www.euphoric-project.eu/?q=node/70). The technical reports and deliverables submitted to the Commission attached to the final report will be made downloadable from the website when approved.

The following papers were prepared during the project. When public available the PDF file was uploaded (http://www.euphoric-project.eu/?q=node/360).

- C. Morciano, G. Badoni, P. D'Errigo, F. Seccareccia and M.Torre " Indicators and outcome assessment models in public health: the European project EUPHORIC". Notiziario dell’Istituto Superiore di Sanità 2006;19 (12): 3-6
- M. Torre, C. Morciano, P. D’Errigo, A. Allepuz, D. Fusco, U. Häkkinen, G. Labek, K. Lyubomirova, J. Marrugat, D. Psaltopoulou, E. Taioli, W.Ye “The EUPHORIC project: outcome indicators collection in Europe. Results of the first phase”. Presented as a poster at the 15th EUPHA Conference and downloadable from the project website. The submitted abstract was published in the European Journal of Public Health, 2007, Volume 17, Supplement 2:213 (Annex 2)
- Bosch X, Loma-Osorio P, Marrugat JJ “Platelet glycoprotein IIb/IIIa blockers for percutaneous coronary intervention, and as initial treatment in Non-ST segment elevation Acute Coronary Syndromes”. The systematic review of the literature was completed by partner IMAS-IMIM and published in the Cochrane Library used in the clinical field as the basis for evidence-based medicine practice. Its aim was to release a clinical recommendation on the use of GPIIbIIIa platelet inhibitors in percutaneous revascularization (Deliverable n. 7)
- M. Torre, V. Manno, A. Allepuz, S. Behar, R. Bellocco, D. Fusco, U. Häkkinen, G. Labek, K. Lyubomirova, J. Marrugat, S. Mathis, D. Psaltopoulou " The EUPHORIC project: outcome indicators collection in Europe. Results of the second phase (pilot)". Presented as a poster at the 16th EUPHA Conference and downloadable from the project website. The submitted abstract was published in the European Journal of Public Health 2008, Volume 18, Supplement 1: 197 (Annex 3)
- G. Baglio, F. Sera, S. Cardo, E. Romanini, G. Guasticchi, G. Labek, M. Torre. The validity of hospital administrative data for outcome measurement after hip replacement. Italian Journal of Public Health 2009 (in press)
- Partner STAKES introduced the outcome indicators (considering years 1998-2005) in their national context during seminars organized in May 2007 and 2008. Reports were published about the use of outcome indicators in Finland for the following topics: AMI, very low birth weight infants, stroke, hip and knee replacements, Schizophrenia, CABG and PTCA (available at http://info.stakes.fi/perfect/FI/tilastotuotteet/index.htm; http://info.stakes.fi/perfect/FI/tilastotuotteet/index.htm)
- U. Häkkinen, T. Kurki, A. Vento and M. Peltola. Risk adjustment in coronary bypass grafting: how EuroSCORE is related to cost, health related quality of life, and cost-effectiveness (submitted to Health Economics)

- A. Paladin, M. Torre, M. Costantini. Il progetto EUPHORIC. CASPUR - Annual Report 2009.

Problems encountered

Impossible to define the subcontract with the technological partner for the website construction until the advance payment was made available (June 2006).

All the problems encountered in reorganizing the project were reflected in the delay in organizing the dissemination activities. The involvement of a scientific publisher was not foreseen in the original contract.

How problems were resolved

In June 2006, the advance payment was delivered to the partners, which was included in the original Grant Agreement. The activities related to the set up of the website started in September 2006. The reorganization of the overall budget, following the withdrawal of GRI, allowed the project leader to agree with the Commission in carrying out a set of additional activities related to the dissemination of the results. A subcontract with the scientific publisher Zadig was signed in June 2008.

Activities planned for the next period

A detailed description of the planned activities is available in the dissemination plan (Deliverable n. 5). Moreover, since the results achieved in the cardiovascular pilot are of great interest for future projects (namely its web-based tool that allows for hospitals to confidentially self-benchmark their in-house mortality rate) they will also be disseminated in the HOPE (European Hospitals and Healthcare Federation) network.

WP 3 Liaison with other EU projects, EU programmes and health stakeholders

In general, the results achieved in a project increase their value if they are shared in as wide as possible context. Therefore, it is important not to work in an isolated situation but act in being part of a network by establishing as many synapses as possible.

Thus, the aim of WP 3 “Liaison with other EU projects, EU programmes and health stakeholders” was to establish connections with key persons participating in projects currently running in Europe that could have connections and/or interests in outcome research or were using similar methodologies even if they did not focus on outcome research. In this way, it was possible to create synergies and share knowledge by also bridging different fields.

Participation in the HSWP and connection with the ECHIM project and the Working Party on Health Indicators opened several opportunities to establish useful contacts.

In particular, cooperation with the ECHIM project and the Working Party on Health Indicators was mandatory in order to ensure that the indicators, presentation and methods were compatible with ECHI.

EUPHORIC was distinctive in that it analyzed outcome indicators and most of them could be considered complementary to those already listed in the International Compendium of Health Indicators (ICHI list).

Activities undertaken

During the third coordination meeting (Luxembourg, April 2007), partner STAKES was appointed as coordinator of this WP. Contacts with the following projects were established: ECHIM, eHID, EUnetHTA, EUGLOREH, OECD (Health Quality Indicators Project), HDP, and the European Patients' Forum. A short reference and the links to the respective websites were included on the EUPHORIC project website (http://www.euphoric-project.eu/?q=node/361).

ECHIM

The project coordinator (ISS) and the partner STAKES contacted the ECHIM project secretariats (KTL and STAKES, Helsinki, Dr. Arpo Aromaa; ISS, Rome, Dr. Emanuele Scafato). As soon as it was available (April 2007), the first deliverable "Survey: result of the first phase", including the list of the 54 outcome indicators, circulated within the ECHIM network. After, EUPHORIC was asked to submit a set of indicators to be considered on the ECHI short list. The following four indicators were selected: [AMI case fatality rate (or survival); CABG case fatality rate; revision rate (orthopaedic); revision burden rate (orthopaedic)] (Deliverable n. 4).

The definition of one of them (AMI 30-day in-hospital case fatality rate) was included in the documentation sheets for the ECHI short list indicators (www.echim.org/docs/documentation_sheets.pdf) and in the ECHIM final report (www.echim.org/docs/ECHIM_final_report.pdf).

Dr. Arpo Aromaa, ECHIM project leader, attended the final workshop in Rome in December 2008 where he gave a presentation on connections between ECHIM and EUPHORIC projects. The role of ECHIM is to coordinate the whole health indicator system. So far, they have implemented the ECHI short list but the next level will include, for example, outcome indicators.

eHID

The coordinator of the eHID project, Dr. Douglas Fleming, was contacted by the project leader during the 8th HSWP meeting. Reports were exchanged. eHID focussed on information collected by GP for four specific indicators: incidence and prevalence of diabetes, burden of mental illness, and the prevalence of ischaemic heart disease. Unfortunately the eHID data available were not useful for the cardiovascular project since their analysis referred to British local prevalences.

EUnetHTA

After the 3rd Project coordination meeting (Luxembourg, April 2007) the leader of the orthopaedic pilot, Dr. Gerold Labek (EAR), contacted EUnetHTA via the beneficiary partner CAHTA (now AQURA) in Barcelona, Spain and a meeting was organized. During the meeting both projects were presented. Taking into account the situation of both projects (EUnetHTA was in its final stage), it was stated that at that time it was not possible and reasonable to establish direct cooperation. However, it was agreed that cooperation in potential future projects concerning health technology assessment and market monitoring was recommended. Bilateral information was agreed. The two partners of EUnetHTA (CAHTA, Spain, and LBI-HTA, Austria) were included as collaborating partners of EUPHORIC since their interests, ongoing activities, and competence were complementary to EUPHORIC.

On 23 January 2008, the link to the EUPHORIC website was added to the EUnetHTA home page (http://www.eunethta.net/HTA/HTA_Networks/).

EUGLOREH

The project leader, Marina Torre, contacted Dr. Luciano Vittozzi, the project leader of the EUGLOREH project. The aim of this project was to produce a report about health in Europe by

the summer 2008. It was agreed to include in the report the contribution related to outcome research and to EUPHORIC in a specific "Focus box" (Annex 4). The report was made available as an internet document on the EUGLOREH website after its official presentation (held on 20 March 2009) (http://www.eugloreh.it/default.do).

OECD

Dr. Päivi Hämäläinen, Finnish coordinator of the OECD Health Quality Indicator Project (HCQI), was invited to the 4th Project coordination meeting (Helsinki, 9 October 2007). It was agreed that EUPHORIC would cooperate with the OECD in order to share and mutually disseminate the results in both networks. Partner STAKES coordinated this activity. Sandra Garcia Armesto, the coordinator of the HCQI project was invited to the final EUPHORIC workshop (Rome, 2008) where she gave a presentation on the connections between the two projects. She promised to cooperate in disseminating the results by using the OECD network.

HDP

The project leader met Dr. Olli Nylander, Finnish coordinator of the Hospital Data Project, during the 8th HSWP meeting and asked partner STAKES to invite him to the 4th Project coordination meeting (Helsinki, 9 October 2007). Co-operation with the HDP was useful in gathering specific information needed in the pilot as well as generally assessing international comparability of hospital discharge data when they are used in calculating outcome indicators. Professor Björn Smedby, a leader of the HDP Expert Group that developed a short list of procedures for international comparison, was invited to the final EUPHORIC workshop (Rome, 2008). Based on the work of the expert group, Björn Smedby analyzed the problems relating to EUPHORIC indicators when they are calculated using hospital discharge registers. He recommended defining the selected outcome indicators more carefully (diagnoses, procedures) before using them. Moreover, the coding and registration differences between the countries should also be taken into account. The collection of the indicators was done during the first phase of the project (2005) and paved the way to defining the pilot. However, since then coding and registration procedures have changed in most of the European countries, and therefore, it was agreed that the EUPHORIC list should be considered as a starting point that, if used now, needs to be updated.

European patients' forum

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. The EUPHORIC project leader agreed with Dr. Roxana Radulescu during the 9th HSWP meeting (Luxembourg, 19-20 November 2007) and with Dr. Nicola Bedlington during the 10th HSWP meeting (Luxembourg, 15-16 July 2008) to establish this kind of cooperation. EPF gave EUPHORIC useful contacts and participated in the virtual table (see WP 2 and Deliverable n. 5 "Dissemination plan").

Problems encountered

In the first phase, the standstill that occurred with the project related to the administrative problems and prevented the regular development of this WP.

How problems were resolved

Working at a constant rate after the official signing of the amendment.

The participation of the project leader in the HSWP meetings offered the opportunity to establish useful contacts with other EU projects and institutions.

3.2 Activities related to project objectives (core work packages)

WP 4 Indicators development

The usefulness of outcome indicators is widely documented in the literature since they allow:

- comparative evaluation of hospital performances
- comparative evaluation between groups of facilities with similar organizational and/or process characteristics (for example, treatment volumes, technological equipment)
- comparative evaluation between populations resident in different areas or of different socio-economic status
- analysis of a trend over a period of time.

The aim of the WP 4 was to achieve the following specific objectives:

- Create a list of diseases amenable to receiving medical procedures whose quality can be assessed in terms of outcome.
- Devise a set of theoretical indicators to assess the quality of procedures used on key diseases and based on outcome.
- Select diseases and procedures suitable for a pilot study to test some indicators.

The activities related to this WP consisted in a survey aimed at defining the necessary tools and operational conditions to be used in the experimental phase (pilot) and in coordination with the Finnish project PERFECT. The results achieved by this WP were collected in the Deliverable n. 1 “Survey: the first phase of the project” and in some reports published by partner STAKES (available on the STAKES website).

Methodology applied as planned

The survey was developed in the first two years of activity and was organized in three phases:

1. Defining a list of outcome indicators.
2. Assessing the current situation about outcome indicators in the participant countries.
3. Selecting diseases and procedures to test some indicators in the experimental phase (pilot).

Coordination with the Finnish project PERFECT was carried out by partner STAKES.

1. Defining a list of outcome indicators

Defining the indicators list was performed during the first year of activity (2005) using the following tasks: literature review, inventory of the existing studies, collecting outcome indicators, preparation of summary tables of outcome indicators and list of procedures.

The starting point was the experience consolidated within the “Outcome Measurement” research of the Italian Mattoni project launched in 2003 by the Italian Ministry of Health in order to redesign the national health system. The aim of this research line was “to identify and experiment suitable methodologies to define, measure and evaluate outcomes”.

A proposal was made to share with all of the partners the methodological approach adopted in the Italian Outcome Mattoni project. Therefore, it was decided to update and integrate the first results obtained in Italy by taking into account the different contexts of the participating countries. This was the first attempt at a cross border sharing of the outcome research

knowledge of each partner and gave added value to each expertise through the synergy derived from the EUPHORIC consortium.

Therefore, a literature search of the outcome studies as well as a review of risk adjustment methods to compare health care outcomes were performed by all the partners on the PubMed database. Moreover, the "outcome" related websites were explored worldwide (~40). The main purpose of this analysis was to identify those validated outcome indicators usually adopted in European and Extra-European countries that could be a good starting point for the introduction of outcome evaluation in the European context. The result of this analysis was the selection of nine areas of pathology (cardiovascular disease and surgery, cancer, infectious disease, other chronic diseases, orthopaedics, transplantation, emergency, neonatal/maternal, miscellanea) and a preliminary list of outcome indicators adopted in European and Extra-European countries.

The final list of outcome indicators was defined on the basis of the following selection criteria: availability, relevance to clinical level, relevance to policy level and to the international scientific community.

Therefore, the following classes of outcome indicators, which are appropriate to monitor health care quality, were identified:

- volume indicators
- mortality indicators for in patient procedures
- mortality indicators for in patient conditions
- utilization indicators
- survival indicators.

On the basis of the literature review, during the second year of activity, a summary sheet for each indicator containing the following information was prepared: title, rationale, numerator, denominator, statistical methods, how to use it, and references. All the sheets were collected in the Deliverable n. 6 "Detailed sheets of the collected outcome indicators (long list)".

Following a request by the HSWP, received on 29 May 2007, EUPHORIC contributed to the preparation of the glossary by providing information about "Best practices/Benchmarking". The submitted glossary was then updated following the criteria agreed to during the 10th HSWP meeting (Luxembourg, July 2008) and organized in a document that was uploaded onto the project website (Deliverable n. 2). The following partners participated: ISS, DEASL, KI, EAR-EFORT, IMAS-IMIM.

2. Assessing the current situation about outcome indicators in the participant countries

In order to assess the current situation about outcome indicators in the participant countries in terms of data availability and comparability, an *ad hoc* designed questionnaire consisting of four parts was organized by gathering a collection of information from the participating countries about their internal organization regarding health care system and health data sources available for the selected outcome indicators. All the information collected using the questionnaire was further uploaded onto the website in the browseable web-based database (see WP 6).

The first part was aimed at gathering information from each participant country about the political-demographical situation and the health care system organization. The participants were also requested to give a brief description of the method employed in filling in their respective questionnaire and to give an overview of the current situation regarding the data sources available in their country for possible testing of the selected outcome indicators.

The second part requested each partner to provide detailed information about the source of data existing in their respective country regarding a list of diseases/procedures within the selected nine areas of interest. For each disease/procedure, the following were specified:

- covered area (national, regional, other)
- electronic form (yes/no)
- type of data source
- linkage with other archives (e.g. hospital discharge, mortality records)
- notes.

The third part was aimed at listing databases or registers or other studies that could be active within two years after the beginning of EUPHORIC.

The fourth part of the questionnaire aimed at assessing the current situation regarding the possibility of testing the selected outcome indicators in each country using "risk adjustment methods". The indicator profile was specified as follows:

- outcome indicators number
- source of data
- crude/adjusted (if adjusted it was specified by: age, gender comorbidities, other confounding factors)
- age range
- disaggregated by: gender, hospital, geographical area, national, other.

It should be pointed out that all the information gathered could not be exhaustive of all the existing sources of data at a local and a national level.

3. Selecting diseases and procedures to test some indicators in the experimental phase (pilot)

The aim of this task was the assessment of possibly defining a common outcome indicators set to be tested during the experimental phase. The selection was based on the data collected during the survey.

Among the areas with the highest burden of diseases, cardiovascular and orthopaedics were chosen for the pilots' implementation on the basis of the following criteria:

- high impact in public health
- not previously investigated by other EU projects (in terms of outcome measurements)
- availability of expertise inside the EUPHORIC consortium
- possibility of receiving data which is available in the countries participating in the EUPHORIC consortium.

Within the two areas, the following procedures were selected considering their high prevalence: acute coronary syndrome for the cardiovascular pilot and arthroplasty for the orthopaedic pilot.

Coordination with the Finnish project PERFECT (by the partner STAKES)

The outcome indicators were introduced by the Finnish partner STAKES at seminars in 2006 and May 2007, referring to the years 1998-2005. Five basic reports on indicators were published (see WP 2 Dissemination strategy/publications and reports). At present, register-based indicators (both at the regional and hospital levels) on the content of care, costs and outcomes between 1998 and 2005 are available for seven health problems. The indicators are available on the internet and they will be routinely updated using more recent information. They have been widely used in local decision making and have also been discussed in the media. The project has given a new dimension to the benchmarking of care: data that directly help the local decision makers since they can compare their own performance by using cost or process indicators as well as outcomes and information on the relationship between costs, process, and outcomes. An example of the practical effect of the project is the implementation of an auditing process in one university hospitals after receiving data on the relatively high mortality of low birth weight infants. In addition, the Ministry of Social Affairs and Health uses the information in their

strategic planning: the indicator developed in the project will be used to evaluate the development of regional differences in the outcomes of specialized care in the National Development Project for Social and Health services 2008–2011. The project researchers produced several manuscripts of which some have already been published. The results of the project indicate, among other things, a positive trend in the development of outcomes in all disease groups. However, the regional and hospital level variations in outcomes and costs of treating the seven diseases are much higher than the overall annual variation and have been rather stable since the late 1990s. An analysis of the regional differences reveals a high potential to improve efficiency by reducing costs and improving outcomes.

Involvement of partners and target groups

All the partners participated in the data collection. The following partners participated in the preparation of the detailed sheets describing the indicators: ISS, DEASL, NKUA, EAR.

In recent years, STAKES has established seven expert groups in order to develop outcome indicators for hospital care in the Finnish national context. The groups include consultants, health professionals, participants of scientific societies and health care providers as well as experts in health economics and statistics. These expert groups focus on several indicators on outcome and costs, the following of which are also included in EUPHORIC:

- acute myocardial infarctions including, PTCA GABG
- hip fracture
- hip and knee replacements
- very low birth weight infants
- stroke.

Coordination with other projects or activities

In order to carry out these activities, some beneficiaries cooperated with other projects actively running at the same time in their countries:

- Project PERFECT in Finland (http://info.stakes.fi/perfect/EN/index.htm). Partner STAKES-CHESS coordinated the PERFECT project in Finland (PERFormance, Effectiveness and Cost of Treatment episodes, http://info.stakes.fi/perfect/EN/index.htm). The project aimed at developing methods for register-based measurement of the cost- effectiveness of treatment. It also aimed at creating a comparative database that shows the treatments given and to compare their costs and effectiveness (outcomes) between countries, hospitals, hospital districts, regions and population groups.
  From the Finnish perspective, the EUPHORIC and PERFECT projects were coordinated so that the Finnish part of the international comparative research for EUPHORIC was done together in close cooperation with the PERFECT project. PERFECT was a joint project by the Social Insurance Institution of Finland, STAKES and university hospital districts that covered the period 2004-2008. The project, which was part of the Academy of Finland's Research Programme on Health Services Research, was also funded by the Finnish Funding Agency of Technology and Innovation (FinnWELL - Future Health Care Technology Programme) and SITRA (the Finnish Innovation Fund).
- Project Mattoni in Italy (http://www.mattoni.ministerosalute.it/). The Mattoni project (2004-2007) published its final report in February 2007. During the project, seven areas were selected and 43 indicators developed. The first list, elaborated by the Mattoni project, was presented by the ISS to the EUPHORIC consortium as a starting basis to develop a final list to be used in a European context. The aim of the Mattoni project was to carry out a description of the Italian health system situation by providing benchmarking among regions and hospitals. By using this as a starting point, EUPHORIC expanded it to an international context. Therefore, the methodology developed in the Mattoni project (based on the

possibility of using risk adjustment methods) was adopted and adapted by the EUPHORIC project in order to provide a thorough analysis of the different contexts of the participating countries. Moreover, not all the indicators selected by the Mattoni project resulted as useful in achieving the EUPHORIC objectives, since most of them referred to the particular Italian context. Therefore, the proposed list was updated considering both the literature research performed by each partner and their experience in the specific fields. As a result, a long list consisting of 54 outcome indicators in nine areas of pathology was defined.

Outcomes and deliverables achieved

- Deliverable n. 1 “Survey: results of the first phase”
- Deliverable n. 2 “Glossary”
- Deliverable n. 6 “Detailed sheets of the collected outcome indicators (long list)”.

Publications by partners STAKES:

1. Korvenranta 1 E, Linna M, Häkkinen, U Peltola M, Andersson S, Gissler M, Hallman M, Korvenranta H, Jaana Leipälä J, Rautava L, Tammela O, Lehtonen L. PERFECT Preterm Infant Study Group. Differences in the length of initial hospital stay in very preterm infants. Acta Pædiatrica 2007 96, pp. 1416-1420.
2. Rautava L, Lehtonen L, Peltola M, Korvenranta E, Korvenranta H, Linna M, Hallman M, Andersson S, Gissler M, Leipälä J, Tammela O, Häkkinen U, PERFECT Preterm Infant Study Group. The Effect of Birth in Secondary or Tertiary Level Hospitals in Finland on Mortality in Very Preterm Infants: A Birth Register Study. Pediatrics 2007; 119: e257-e263 (downloadable from http://info.stakes.fi/perfect/EN/publications/index.htm)

Problems encountered

Interpretation and compilation of the questionnaire.

How problems were resolved

Instruction given by phone and via e-mail.

WP 5 Development of adverse outcome risk indicators in real clinical and register databases, and their possible use in administrative systematic databases. (pilot)

The results obtained from the survey paved the way for the preparation of the pilot phase. In fact, retrieving the country specific information through the analysis of the questionnaire completed by each participant permitted the assessment of the availability of existing data in the respective countries. Therefore, cardiovascular and orthopaedic areas of pathology were taken into consideration for the pilot study because of their high clinical and political relevance and also because all the participants were able to provide information in these areas.

The originally proposed organization of the pilot was based on an active collection of data and the use of existing databases. However, on the basis of the results obtained during the survey phase (Deliverable n. 1), it appeared that the use of existing recent population-based registers to fit predictive functions of outcome after the selected procedures, and additionally, the validation of these functions on routinely collected hospital discharge data were feasible and more efficient and effective for EUPHORIC. Moreover, the outputs produced were more easily implemented in the routine health information flow systems. Therefore, as reported in the first interim report submitted on 9 August 2007, the pilot phase was organized so as to use only these types of data. Prof. Jaume Marrugat (partner IMAS-IMIM, Spain) and Dr. Gerold Labek

(partner EAR-EFORT, Austria) were appointed as leaders of the cardiovascular and the orthopaedic pilots respectively. Special efforts were made to enlarge the consortium by including as many countries and databases as possible.

For a better description of the activities performed in this WP, the following sub-work packages were considered:

- 5.1 Cardiovascular pilot
- 5.2 Orthopaedic pilot.

During the meeting held in Helsinki on 8-9 October 2007, the importance of considering all the activities related to risk adjustment and statistics as a separate sub-work package was highlighted. Therefore, with respect to the first interim report, the sub-work package 5.3 "Use of the available sources of information in participant countries in order to develop a standardized statistical methodology for comparative evaluation of outcomes" was added. Partner EAR offered their help for the coordination of the WP 5.3. Afterwards, partner DEASL proposed their candidature for this job. The leadership of partner DEASL was approved during the meeting held in Stockholm on 31 January 2008 by the main coordinator (ISS) and partners involved in the orthopaedic pilot (EAR, STAKES, KI). Partners IMAS-IMIM and NKUA sent their approval by e-mail or telephone.

Since acute coronary syndrome and arthroplasty were selected to be tested in the EUPHORIC pilots, partner STAKES started two special research projects for these topics in Finland in 2007. Regarding CABG and PTCA procedures, they gathered data which were similar to those available from Spain in order to analyze outcome differences between hospitals during the years 1998-2005. The first results of the study were reported at a seminar on 8 February 2008. A paper was prepared and submitted for publication (1). Similar studies were started for hip and knee replacements.

1) Unto Häkkinen, Tuula Kurki, Antti Vento and Mikko Peltola. Risk adjustment in coronary bypass grafting: how EuroSCORE is related to cost, health related quality of life, and cost-effectiveness (submitted to Health Economics).

WP 5.1 Cardiovascular pilot

Acute coronary syndrome (ACS) was selected for the EUPHORIC cardiovascular (CV) pilot study since it was judged to be the easiest and most appropriate: admission is always required, there are many ongoing registers, and in-hospital and 6-month procedure-use and -outcome are relatively easy to monitor. Myocardial infarction is the individual cause of death which causes the highest number of deaths in developed countries every year (cardiovascular diseases in general caused more than 58 million deaths in the world in 2005). Morbidity is also a major health challenge since the number of admissions of acute coronary syndrome patients (more than half of whom develop myocardial infarction) represents a very high proportion of total admissions and has increased almost five times in the last 20 years in Spain, for example.

The specific aims of the cardiovascular pilot, set up after some modifications since the last report and described in detail in the cardiovascular pilot protocol (Deliverable n. 8), were as follows:

1. to define a simple set of factors that determine quality of health care outcome (in-hospital case fatality) in patients who received thrombolysis, underwent coronary angiography, or percutaneous interventions or were treated for myocardial infarction or unstable angina. These indicators were analyzed in the context of characteristics at individual, hospital and country levels
2. to develop a set of tools (mathematical functions) to benchmark European hospitals by their observed indicators (in-hospital case fatality) according to the expected adjusted risk of the outcome that provides systematic information to end-users (doctors, health staff, health

administration, decision makers, policy makers, EU population and public health stakeholders)

3. to test the functions that estimate the indicators with regard to information obtained routinely for administrative purposes
4. to develop and update a systematic review of the literature on the efficacy of GPIIb-IIIa inhibitors in ACS.

Methodology applied as planned

The cardiovascular pilot started in March 2007 when Prof. Jaume Marrugat, principal investigator of the IMAS-IMIM partner, accepted the leadership. A description of the methodology and of the development of the cardiovascular pilot is provided in the following paragraphs. More details are available in both the cardiovascular pilot protocol (Deliverable n. 8) and the cardiovascular pilot final report (Deliverable n. 8.1).

Cardiovascular pilot development

(Summary: see Deliverable n. 8.1 for more detailed information)

The protocol of the pilot study initially included the following **procedures** related to acute coronary syndrome that needed to be evaluated in the preliminary analyses before fitting the desired functions:

- coronary artery bypass graft (CABG)
- coronary angiography
- thrombolysis
- percutaneous intervention (angioplasty with or without stenting)
- general MI management
- general unstable angina management
- GPIIbIIIa blocker use (meta-analysis).

The **outcomes** considered included:

- mortality (case fatality) at 30 days after the selected procedures
- in-hospital mortality (case fatality)
- a combined end-point of 30-day death, re-infarction or angina post-infarction.

Chronological description of the development of the cardiovascular pilot

The initial steps included a thorough discussion on the best approach to achieve the desired benchmarking models. Beta versions were sought that will need validation in the future with real data from European hospitals.

Databases from four European registers, to which access was possible, were merged: MASCARA 2005, ACSIS 2004 and 2006, and Euro Heart Survey of the European Society of Cardiology (EHS-ESC) 2000 and 2005. Data cleansing and homogenization of the resulting combined databases of 26,762 patients were completed. Three of the five registers used in EUPHORIC were representative of Spain (MASCARA with 32 hospitals) and Israel (ACSIS 2004 and ACSIS 2006 with 25 hospitals each); the other two (EHS-ESC 2000 and 2005) included 29 countries. However, the total of 285 participating hospitals was not representative of the countries of origin, and patient consecutiveness during recruitment was not guaranteed.

Hospital, country, and individual characteristics were taken into account for risk adjustment in the analyses being probably at the origin of varying outcome of procedures used in ACS.

The preliminary analyses reported in the 5th Project coordination meeting (Innsbruck, March 2008) suggested that 30-day and 6-month event and mortality rates were not suitable for the analysis with these databases given the high number of missing values and the low probability that hospitals have such information available: in-hospital mortality (case fatality) seemed to be the more robust and pragmatic endpoint with very little missing values. AMI and unstable

angina management, as well as coronary angiography, thrombolysis and percutaneous intervention use, were confirmed to be suitable procedures to assess the functions owing to a sufficient number of events observed and to the number of procedures performed in the participants of the joint databases.

No important differences in any model in variable coefficient estimates (as seen in the odds ratios (ORs) and their 95% confidence intervals) were found in a sensitivity analysis when results in the entire population were compared with those obtained when hospitals with less than 50 patients were excluded, and with those obtained when countries with less than 100 patients were excluded. Coefficients (ln(ORs)) obtained were, therefore, suitable for the CV pilot's purpose of attempting to benchmark European hospitals in this phase. This multilevel analysis provided a percentile system with the interval of expected outcome values given the country, hospital and individual characteristics entered. Prospective data will be needed in the future to validate this initial proposal.

Statistical analyses designed in the final version protocol (Deliverable n. 8) were completed.

The nine necessary mathematical functions with different combinations of data availability in multilevel models that include country level characteristics (gross national income per capita, life expectancy at birth and age-adjusted coronary heart disease mortality rates), hospital level characteristics (university hospital, on-site catheterization laboratory and on-site cardiac surgery) and individual characteristics (mean age, proportion of patients of female gender, with hypertension, with diabetes, and with history of cardiovascular disease) were developed. Country health basic information, as well as the characteristics of those hospitals that participated in the component registers of the joint database (ESC database), were gathered from the partners using an *ad hoc* questionnaire (included in the cardiovascular pilot protocol, Deliverable n. 8), developed by the cardiovascular pilot leader (partner IMAS-IMIM) involving partners ISS, EAR, NKUA and DEASL, and from the WHO Statistical Information System (WHOSIS) (http://www.who.int/whosis/database/core/core_select.cfm).

The comparison was established in terms of procedure use and outcome rate risk by procedure benchmarking (interquartile and 5th and 95th percentiles were provided for hospitals with similar characteristics to those stated by the tested European hospital).

The testing of the functions was completed with several simulations of health information combinations and hospital characteristics both in the generic models. The website implementation of the function was verified and all the partners checked it.

Since almost all the indicators in Finland were available from Finnish health system registers, partner STAKES also played an important role in the pilot phase and real hospital data from that country were taken to test the functions (**Objective 3**). These results are presented in the final report of the EUPHORIC cardiovascular pilot (Deliverable n. 8.1).

Involvement of partners and target groups

During the 3rd Project coordination meeting held in Luxembourg on 24 April 2007, the availability of other partners was investigated. After the 4th Project coordination meeting, held in Helsinki in October 2007, it was decided to prepare an agreement in order to share anonymized hospital discharge data between partners IMAS-IMIM and STAKES.

During the first semester of the CV pilot activity in 2007, partner IMAS-IMIM developed preliminary statistical analyses to evaluate whether the use of information from the registers could be applied to health information systems in terms of checking for patient case mix and for the most important clinical variables for comparative evaluation of outcomes and benchmarking.

Very fruitful cooperation was established with the collaborating partner ISPHA (Israel) who provided the ACS-EHS and ACSIS databases; and the Cardiology Dpt of the Hospital Vall d'Hebron, Barcelona (Spain) who permitted the use of the MASCARA data resulting in a large

(more than 25,000 ACS patients) database that allowed to fit the necessary models; as well as partner STAKES (Finland) who sent the aggregated data from more than 25 Finnish hospitals which were used in a preliminary validation of the functions. The technological partner CASPUR implemented the function on the website in cooperation with the ISS who supported this activity.

Coordination with other projects or activities

An attempt to set up collaboration with the coordinator of the Euro Heart Survey Programme from the European Society of Cardiology, Dr. Anselm Gitt, was unsuccessful. However, thanks to Prof. Marrugat, a formal invitation was made to the former coordinator of the Euro Heart Survey Programme, Dr. Shlomo Behar. Subsequently, this led to very fruitful cooperation with the ISPHA (Israel), who became a EUPHORIC collaborating partner on 21 December 2007 and that made it possible to include the databases detailed below in the cardiovascular pilot.

Following a specific request by the ECHI project coordinator (Dr. Pieter Kramers) two indicators relating to the cardiovascular area were proposed as candidates to be included in the ECHIM short list (Deliverable n. 4). The definition of one of them (AMI 30-day in-hospital case fatality rate) was included in the documentation sheets for the ECHI short list indicators (www.echim.org/docs/documentation_sheets.pdf) and in the ECHIM final report (www.echim.org/docs/ECHIM_final_report.pdf).

Outcomes and deliverables achieved

- Prof. Jaume Marrugat, principal investigator of the IMAS-IMIM partner, accepted the leadership of the cardiovascular pilot.
- Update of the objectives of work package 5.1 (see above).
- Development of a proper protocol for the cardiovascular pilot study (Deliverable n. 8).
- **Outcomes for Objective 1**
  A number of European investigators were contacted to cooperate with other existing projects and/or registers. The aim of these contacts was to gather myocardial infarction or acute coronary syndrome patient databases. DG SANCO Unit C2 supported the pilot leader in contacting the EHS project and in checking the rules to be followed to transfer data among partners. The following databases' owners committed to participating in the EUPHORIC cardiovascular pilot study in December 2007 were:
  1. MASCARA Study 2005: approximately 8,500 acute coronary syndrome patients from 37 Spanish hospitals. Prof. Dr. Gaietà Permanyer, Cardiology Dpt, Hospital Vall d'Hebron, Barcelona, Spain.
  2. EURO Heart Survey 2000 on acute coronary syndrome: approximately 3,000 myocardial infarction patients from more than 20 European countries. Prof. Shlomo Behar, Israel.
  3. EURO Heart Survey 2005 on acute coronary syndrome: approximately 6,500 acute coronary syndrome patients from more than 20 European countries. Prof. Shlomo Behar, Israel.
  4. Israeli Centre for Disease Control on the platform of ACSIS Israel Heart Society was also willing to cooperate and sent the ACSIS 2004 and 2006 databases (4,000 patients from 25 hospitals). Prof. Shlomo Behar, Israel.
- The databases were joined and the analyses that led to outcome selection and procedure selection for European hospital benchmarking were undertaken.
- IMAS-IMIM developed the necessary data management and prepared the final CV pilot report (Deliverable n. 8.1).

- **Outcomes for Objective 2**
  The mathematical functions were developed at IMAS-IMIM with the European register databases collected in objective 1.
- **Outcomes for Objective 3**
  Aggregated patients and hospital data from partner STAKES (Finland) were used to analyze the accuracy and precision of the predictions of the benchmarking functions developed in the EUPHORIC cardiovascular pilot with administrative data.
- **Outcomes for Objective 4**
  The assessment of drug use in the assessed procedures was not foreseen in the initial protocol. Platelet GPIIbIIIa blocker use is currently an important practice in PTCA procedures: partner IMAS-IMIM deemed it necessary to assess its usefulness in a meta-analysis that was published in the prestigious Cochrane Library (Deliverable n. 7).
- Initiation of the dissemination plan:
  a. in December 2008, the benchmarking system (developed functions) was implemented by subcontractor CASPUR in the restricted area of the EUPHORIC website for self assessment (benchmarking) of hospitals by the EUPHORIC partners
  b. a draft manuscript with the main results of the WP 5.1 was prepared.

Problems encountered

None after the appointment of the CV pilot leader.

How problems were resolved

Does not apply.

Activities planned for the next period

Implementation of the dissemination plan. Cooperation between EUPHORIC and future projects and involvement of HOPE.

WP 5.2 Orthopaedic pilot

During the 2nd Project coordination meeting held in Rome on 9 June 2006, the associated beneficiary EFORT-EAR, Dr. Gerold Labek, being vice president of EAR (a network of arthroplasty registries in Europe), was put in charge of coordinating the orthopaedic pilot (arthroplasty project). He started organizing the activities even though the formal act of his official inclusion in the project occurred afterwards in January 2007. The amendment signed on 26 January 2007 allowed him to establish their leadership for the orthopaedic pilot, adapt the existing EAR network according to the EUPHORIC requirements, and substantially start their scientific activities.

The aims of the orthopaedic pilot were to:

1. develop outcome indicators for arthroplasty based on the existing national projects and according to the requirements of ongoing European Commission projects
2. summarize the existing projects and the essential issues for success
3. define best practice procedures to develop and operate arthroplasty registers
4. validate the potential contribution of different instruments in the outcome measurement and quality monitoring of medical devices (i.e. registers, meta-analyses of clinical studies, implant failure monitoring systems by the public health institutions, quality control and complaint handling systems by the manufacturers) for a structured outcome measurement and quality control system at the EU level
5. present a detailed description of the outcome related registers and similar datasets in two countries (Sweden, Finland) with a reputable and advanced system in Europe in order to

study the organization and function of the entire outcome and quality monitoring system at a national level.

Methodology applied as planned

From an organizational point of view, EAR carried out the following activities:

- The orthopaedic pilot network was enlarged and included additional collaborating partners, which gave added value to the project by providing their specific expertise.
- In cooperation with partners ISS, KI, STAKES and CAHTA, two *ad hoc* specific questionnaires were developed to: 1) collect information about arthroplasty registers already existing in Europe; 2) collect information about arthroplasty registers existing in Sweden and Finland. Both questionnaires were included in the orthopaedic pilot protocol (Deliverable n. 9).
- The whole concept was agreed at the 4th Project coordination meeting held in Helsinki in October 2007. All partners were requested to start their activities as soon as possible with respect to the time schedule of the entire EUPHORIC project.
- Meetings were organized in Stockholm and Helsinki in order to coordinate the activities and to discuss the findings.
- In the context of active participation in EUPHORIC, EAR worked at the reorganization of the existing arthroplasty registers network. The main aim was to make these sources of data available for their implementation by the European Commission in future regular monitoring and market surveillance activities. Arthroplasty was proposed to the Network of Working Party leaders as an area for future SANCO actions in the health information and knowledge domain.

To achieve the stated objectives, the activities were organized in six sub-work packages:

- *WP 5.2.1: Assessment and summary of the existing arthroplasty registers and related projects*. In this WP, three specific activities were carried out:
  a. a comparative description of the Finnish and Swedish outcome measurement systems in cooperation with partners STAKES and KI (Deliverable n. 9.2 and Deliverable 9.3 respectively)
  b. a summary description of relevant arthroplasty register projects in Europe
  c. the development of a tool to characterize registers done by collaborating partner LBI HTA (Deliverable n. 9.4).
- *WP 5.2.2: Comparison of clinical studies and register results*. In this process, the following issues were dealt with in detail:
  a. bias in different datasets
  b. impact on outcome measurement and monitoring
  c. impact on licensing procedures for medical devices
  d. proposal for adjusted, updated procedures.
- *WP 5.2.3: Quality control mechanisms and quality control procedures by manufacturers.* Using examples from the past few years, the procedures and the reactions of the parties involved were analyzed, and consequently proposals were made for improved procedures with reference to the following issues:
  a. impact on outcome monitoring
  b. impact on licensing procedures for risk class III medical devices.
- *WP 5.2.4: Significance of the indicators proposed from medical expert's point of view*. The indicators in the field of orthopaedics were subjected to critical review from the service provider's point of view and from the perspective of outcome measurement. On the one hand, a comprehensive literature research of leading scientific journals was performed; on the other hand, the indicators were evaluated from a medical perspective with respect to

their applicability as indicators in the clinical field and their usability in implementing practical measures.

- *WP 5.2.5: Public health-related data sources concerning medical device failures, monitoring and their linkage*. A comparative analysis of the data available was performed using the example of the fracture of a total hip arthroplasty component.
- *WP 5.2.6: Summary of basic data concerning the indicators from international databases*. Data were collected from internationally accessible data sources concerning the proposed indicator of "Revision Burden" for artificial joint implants.

During the project, the following additional topics were included in the work plan:

- rationale and value to link outcome data and economic data in a register. A subcontract was signed with the Romanian Arthroplasty Register to prepare a report (Deliverable n. 9.5); a report was requested to the Emilia-Romagna Regional Authority (Italy) (Deliverable n. 9.6)
- link of discharge records with outcome register data. A subcontract with the Institute for Biostatistics at the University of Innsbruck was signed (Deliverable n. 9.7)
- study a hypothesis concerning follow up of artificial joint implants by applying an updated method to respect the risk of failure and financial aspects in cooperation with the University of Halle (Saale) (Deliverable n. 9.8).

Involvement of partners and target groups

- KI, STAKES, ISS, and the following collaborating partners: TILAK, LBI-HTA, CAHTA, SOFCOT, SAR, BQS. In particular, STAKES and KI carried out the assessment of the outcome research and monitoring system for Finland and Sweden respectively and market monitoring by public health institutions in Europe; LBI-HTA reported on a quality label system for datasets; BQS and SOFCOT contributed to WP 5.2.1 and to the dissemination and, since it was not possible to study French literature due to the limited language skills of the EAR scientific team, negotiations were started to cover this gap in cooperation with SOFCOT after the end of EUPHORIC; SAR, CAHTA and TILAK also contributed to WP 5.2.1 and gave support at local level to all the activities (i.e. CAHTA contacted Spanish institutions and collected the information using the questionnaires). ISS cooperated with the Emilia Romagna region (Italy) in the preparation of a report (Deliverable 9.7) and funded its translation.
- The Romanian Arthroplasty Register, the Medical University Innsbruck, Dept of Biostatistics and Health Economics as well as Mrs Kerstin Pankewitsch from the University Halle (Saale) were involved as subcontractors.
- EFORT (European Federation on National Associations of Orthopaedics and Traumatology; www.efort.org) was involved in order to get access to national institutions and experts in a more convenient way and to support dissemination of the results to the service providers (physicians, hospitals) directly.

Coordination with other projects or activities

EAR – European Arthroplasty Register.

EUnetHTA - European Network for Health Technology Assessment.

Outcomes and deliverables achieved

The results of the orthopaedic pilot were organized in a main report "Orthopaedic pilot final report" (Deliverable n. 9.1) referring to specific technical reports.

In particular the following outcomes and deliverables were produced:

- **Objective 1**
  Two indicators (Revision Rate E8 and Revision Burden E9) were selected and submitted to ECHI with the indicator sheets.
- **Objective 2**
  All relevant projects were described in Deliverable n. 9.2. Conclusions and proposals are available in the main document related to the orthopaedic pilot (Deliverable n. 9.1).
- **Objective 3**
  Based on the activities related to Objective 2 a "Handbook for the Development and Operation of an Outcome Register for Medical Devices" was prepared.
- **Objective 4**
  Since the findings were considered potentially relevant for standards procedures of the EU Commission it was decided to present the background material in detail to support an independent review process by the Commission. The findings are presented in the main document related to the orthopaedic pilot (Deliverable n. 9.1, WPs 5.2.2 and 5.2.3). Details are described in specific technical reports. All the documents will be published after the approval by DG SANCO and DG Enterprise.
- **Objective 5**
  The Finnish and Swedish outcome monitoring systems were described in Deliverable n. 9.2 and Deliverable n. 9.3. Summary conclusions from a supranational point of view are available in the main document related to the orthopaedic pilot (Deliverable n. 9.1).

EUPHORIC cooperated with Laziosanità-Agency for Public Health with regard to their study on the validity of hospital administrative data for outcome measurement after hip replacement, carried out in the Lazio region (Italy). The results will be published in a paper accepted by the Italian Journal of Public Health and will be made available on the project website.

Problems encountered

Administrative difficulties in the official involvement of EFORT-EAR in the role of partner.

The question regarding defining the further participation of partner GRI, which started at the end of May 2007 and ended at the beginning of February 2008, was a hindrance for the planning and development of the orthopaedic pilot protocol.

The delay in handling the withdrawal of GRI led to the deferral in the grant amendment and financial transactions.

How problems were resolved

The request to include EFORT-EAR as a partner was sent in April 2006. In June 2006, all the administrative requirements were satisfied. The partner was officially recognized in January 2007 (signing of the amendment to the contract) and financed in May 2007.

In close cooperation with the project leader and the commission officer, Mr Artur Furtado, partner EAR tried to clarify the availability of GRI by either finding an agreement for future cooperation or defining the withdrawal from the partnership.

Activities planned for the next period

To continue with testing datasets and literature concerning implants sold on the EU market in order to check the base for decisions in retrospect.

To disseminate the results according to the dissemination plan.

WP 5.3 Available sources of information in participant countries in order to develop a standardized statistical methodology for comparative outcomes evaluation

As discussed in the Working Group on Statistics meeting held in Helsinki, Finland on 8 October 2007, and decided in Stockholm, Sweden on January 31 2008, the WP 5.3 was considered a support WP to the two pilots (WP 5.1 and WP 5.2).

The aims of this WP were:

- to describe the general quality and verify the possibility of standardizing the categories and the variables of the data collected for EUPHORIC:
  a. from population or hospital registers, surveys, clinical trials, in the WP 5.1 and WP 5.2
  b. health care systematic information (hospital discharge databases) data.
- to test a standardized methodology for the calculation of the chosen indicators in WP 5.1 and 5.2. To compare the outcomes of the selected pathologies and procedures in individual hospitals within each European country, using health care systematic information (hospital discharge databases) data.

Therefore, there was the real need to have detailed information about the structure of these databases in terms of collected variables and methodology for data collection in order to develop procedures that allow benchmarking of participant hospitals and countries by using routinely collected data (mostly hospital discharge records).

Moreover, the increasing demand for comparative outcomes evaluation requires the development and diffusion of epidemiologic research, the ability to correctly conduct analyses and to interpret results. However, when health care outcomes are used for comparing quality of care across providers, or countries, failure to use robust adjustment methods to control for potential confounders (i.e., variation in patient, hospital or country characteristics) can lead to biased results.

This WP 5.3 coordinated with WPs 5.1 and 5.2 in the quest to define the best standardized adjustment methodology for the calculation of the indicators so as to safely compare outcomes of the selected pathologies and procedures across the participating countries when using health care systematic information (hospital discharge databases) data. A detailed description of the WP 5.3 protocol is given in Deliverable n. 12.

Methodology applied as planned

WP 5.3 collaborated with the cardiovascular (CV) pilot to define the best risk adjustment methodologies for comparative evaluation of outcomes, and to define the CV indicators using data from administrative information systems or clinical records.

Direct standardization procedures using the entire population under study as a reference (the average) were considered the best possible choice. This method, already applied to outcome studies in other fields of health care, uses a fixed effects model which allows all stable characteristics of a unit of analysis to be checked, including those not observed or measured. When hospitals of treatment (or providers) are the exposure of interest, dummy variables representing the hospitals (or providers) are generated and included in a regression model together with the potential confounders selected on a predictive model of the relevant outcome. This method of direct adjustment allows the expected outcomes between hospitals (or providers) to be estimated and compared simultaneously. Therefore, it allows the direct comparison of the performance of each hospital (or provider) with a reference population and with all other hospitals.

WP 5.3 also collaborated with the orthopaedic pilot to choose the best indicators for outcome research. While the two indicators foreseen in the orthopaedic pilot, “Revision Rate” and “Revision Burden Rate”, are fundamental in evaluating outcomes of prostheses from a health

technology assessment point of view, the two most important indicators from a public health point of view for comparative evaluation of outcomes between hospitals concern the hip fracture. The indicators referred to are “Intervention within 48 hours" and "Death within 30 days of arrival at hospital for hip fracture”.

The outcome indicator “Intervention within 48 hours of arrival at hospital for hip fracture” was preferred to the EUPHORIC indicator “In-hospital waiting time for femur fracture surgery” for the following reasons: 1) several studies have shown the advantages of an early surgical approach in hip fracture patients; 2) recently, the Organization for Economic Co-operation and Development (OECD) has included a 48-hour waiting time to surgery in elderly patients with hip fracture in its national quality indicator list; 3) a recent meta-analysis has shown that delaying surgery for 48 or more hours after admission may significantly increase the odds of adverse outcomes.

For both pilots, WP 5.3 recommended to define the indicators using data from administrative information systems, including the Emergency Information System (HEIS) if available, or clinical records. Since studies have highlighted that increasing time between arrival at hospital and receiving effective treatment for AMI and hip fracture may result in worse health outcomes, WP 5.3 recommended modifying the protocols for AMI and hip fracture by including information from the HEIS. Mortality and time to surgery (for fractured hip) should be calculated from arrival at hospital, corresponding to the date of hospital admission or Emergency Room visit. Concerning outcome indicators, the HEIS could also be used as an additional information system in order to increase the probability of finding patient comorbidities to be included in risk adjustment models.

A deliverable about the methodologies related to risk adjustment procedures to be used when comparing data was prepared (Deliverable n. 10). This deliverable can be considered as preparatory to WP 5.3 and was included in it.

In order to identify the risk adjustment methodologies to be applied for comparative evaluation of outcomes in EU states, information was collected on health care information systems and registers in the countries participating in the EUPHORIC project. For this purpose, a short questionnaire on health data collection at local and/or national level was developed and annexed to the protocol (Deliverable n. 12) This questionnaire gathered data on: demographic characteristics of patients, diagnoses and procedures of discharge records, and general information on mortality records. The collected information was summarized in a report (Deliverable n. 12.1). Information on the clinical variables and statistical procedures used in the cardiovascular registers and details about the arthroplasty registers of the participating countries were reported in Deliverable n. 12.2.

In order to evaluate the differences when identifying given diseases by using one or more information sources, the EPIC-Greece study in EUPHORIC performed a specific analysis on cardiovascular diseases (CVDs) (Deliverable n. 12.3).

A study was conducted on acute myocardial infarction (AMI) and hip fracture in order to evaluate whether the same results can be obtained for some outcomes by using the information available from registers or from health care information systems and whether the addition of clinical variables to administrative data improves the accuracy of risk adjustment. The aim of this study was to identify condition-specific clinical variables to determine the difference in terms of comparative evaluation of outcomes between register-based or information system-based risk adjustment models (Deliverable n. 12.4).

Since comparing health care outcomes between providers or countries requires the development of shared extended protocols for outcome indicators, including detailed inclusion/exclusion criteria and variables to be used for risk adjustment, extended protocols were defined for a list of indicators on AMI and hip fracture (Deliverable n. 12.5). In the extended protocols, 30-day mortality was used as one of the outcomes but the use of in-hospital mortality is also recommended when it is not possible to calculate mortality rates by linking

hospital records and death records, which is often based on in-hospital mortality. Rates of death during hospitalization can predict total mortality after admission, but the strength of this association is condition-specific. Some studies have shown that, for acute conditions such as AMI and hip fracture, the use of in-hospital mortality or 30-day mortality for comparative evaluation of outcomes gives similar results.

Since the inclusion within a risk adjustment model of factors that do not actually induce a relevant bias in the estimate of the measure of association may cause a loss of precision and implies additional costs of collecting the relevant information, a statistical procedure, called "Change-in Estimate", was developed for multiple level exposures (i.e, different hospitals) to identify the real confounding variables in comparative evaluation of outcomes (Deliverable n. 12.6).

Since using appropriate risk adjustment models to a hospital's data helps 'level the playing field' so that a hospital can compare its indicator rates to other hospitals more fairly, a report was achieved that included the steps to develop risk adjustment models and the suggested statistical procedures to be used for comparative evaluation of outcomes in the EU area (Deliverable n. 12.7).

In conclusion, the methodology described in WP 5.3 protocol was applied as planned. Administrative databases clearly offer advantages in comparative evaluation of outcome because they are relatively inexpensive and generally cover a large population. However, administrative data also have important drawbacks from a clinical perspective: limitation of ICD coding and absence of many important clinical variables. We started exploring the possibility of collecting information from administrative and clinical databases in order to identify the most important factors to include in risk adjustment models but further analyses are still necessary.

Development of other standardized, more complex statistical procedures for the comparative evaluation of outcomes, in particular Multilevel Modelling and Bayesian Analysis are recommended.

Involvement of partners and target groups

Coordinator: Partner DEASL. Involved partners: IMAS-IMIM, EAR, STAKES, KI, NKUA.

Coordination with other projects or activities

Collaboration with the Hospital Data Project 2 (HDP2) was established and administrative health data information collected by HDP2 was reported for the following countries participating in the EUPHORIC Project: Austria, Finland, France, Germany, Greece, Slovak Republic, Sweden.

Outcomes and deliverables achieved

Deliverable n.10 *Risk adjustment methodologies*. This review is a detailed but easy-reading document with the different risk adjustment methodologies so as to compare health care outcomes.

Deliverable n. 12 *Protocol for risk adjustment and statistics work package*.

Deliverable n. 12.1 *Information on national hospital data collections in the EU states participating in the EUPHORIC project.* This deliverable describes the administrative health data collected within each country participating in the project. Details are provided for each country regarding: period of observation, type and number of hospitals, and individual characteristics of discharge records (demographics, socio-economic indicators, diagnoses, procedures).

Deliverable n. 12.2 *Information from cardiovascular and arthroplasty registries*. This deliverable reports details about the cardiovascular and arthroplasty registers of the participating countries. In particular, available variables are listed and statistical methodology is described for

the cardiovascular registers. Regarding arthroplasty registers, details are given on: basic information, data collection, connection to other data sources, validation of data, statistical analysis, data reporting, and publication of results.

Deliverable n. 12.3 *Identifying cardiovascular diseases (CVDs) by using one or more information sources*. This deliverable evaluates the differences in identifying CVDs by using one or more information sources, in particular by using either a questionnaire or medical records or hospital discharge information and BOTH medical records and hospital discharge information.

Deliverable n. 12.4 *Identifying the clinical variables determining the difference in terms of comparative evaluation of outcomes between register-based or information system-based risk adjustment models*. The objective of this deliverable was to assess whether an AMI-specific and a hip fracture-specific predictive model based on administrative data plus additional clinical variables had better adaptation and performance than corresponding models only based on administrative data, and if adding these clinical variables to hospital administrative data might improve the risk adjustment for interhospital comparisons of AMI/hip fracture outcome rates.

Deliverable n. 12.5 *Extended protocols*. This deliverable includes some extended protocols for outcome indicators and was developed using both 9th and 10th revisions of the International Classification of Diseases (ICD-9 and ICD-10). In particular, the list of indicators includes:

- death within 30 days of admission to hospital with an acute myocardial infarction (AMI)
- death within 30 days of arrival at hospital for an acute myocardial infarction (AMI)
- death within 30 days of arrival at hospital with a fractured hip
- intervention within 48 hours of arrival at hospital for hip fracture.

Deliverable n. 12.6 *Identification and definition of risk factors for comparative evaluation of outcomes - A "change-in" estimate procedure*. Since the selection of the "best" risk adjustment models should aim at the maximum parsimony, this report describes a new statistical procedure aimed at identifying risk factors for comparative evaluation of outcomes: the "Change-in Estimate". This procedure, which selects confounding variables according to the amount of change in the estimate of exposure observed, was developed for multiple level exposures. An SAS programme to implement the "Change-in Estimate" procedure is available by request for all partners.

Deliverable n. 12.7 *Statistical procedures for comparative evaluation of outcomes*. Since the objective of risk adjustment is to identify a model which can accurately predict the outcome while checking for an array of patient risk factors, this deliverable reports the steps to develop risk adjustment models for assessing health care quality. More specifically, different statistical procedures to be applied in the EU area for comparative evaluation of outcomes are described in detail.

Problems encountered

The DEASL was officially recognized as WP 5.3 leader in January 2008.

Difficulties in the official collaboration with HDP (Hospital Data Project).

How problems were resolved

Thanks to Prof. Björn Smedby, it was possible to keep in touch with Dr. Gerrie Lierens and Dr. Mark Boll who provided the metadata gathered by the HDP2 project which were useful in finalizing the analyses.

Activities planned for the next period

Dissemination of EUPHORIC results.

WP 6 Setting up and maintaining indicators database

The subcontract with the Inter-University Consortium for the Application of Super-Computing for Universities and Research (CASPUR - **C**onsorzio interuniversitario per le **A**pplicazioni di **S**upercalcolo **P**er **U**niversità e **R**icerca www.caspur.it) stipulated by ISS in September 2006 to implement the project website also included the activities relating to the setting up and the maintenance of the indicators database. To carry out this task, ISS and CASPUR collaborated very closely from the beginning. The aim of this work package was to set up a database of the indicators selected during the first phase of the project, the survey. The database collects all the information related to the indicators such as the synthetic description of the indicators (definition, numerator and denominator) as well as the detailed information derived from the literature analysis and collected in the indicators sheets (see Deliverable n. 6). The indicators were organized according to the areas of pathology defined during the survey. The same database also includes all the information collected during the survey and relevant to the sources of data available in the participating countries and to the selected indicators. The database is located on the website of the project and has been available to the public since 8 September 2008. A user-friendly operation was developed to search the database.

In 2006, the former EUPHORIC project leader (Fulvia Seccareccia) gave MEDISOFT the task of preparing software aimed at providing data in real time as it comes from several remote terminals on a central server.

Methodology applied as planned

The development of the website started in September 2006. The first beta version of the website and the public part of the website were completed and put online on 9 March 2007. The website is housed at CASPUR and is reachable at www.euphoric-project.eu. Since then the website has been updated as soon as new documents and results are made available. In particular, the following activities were carried out:

- an electronic form was developed to input and validate the information collected during the survey phase. This information relates to the data sources available in the participating countries and the outcome indicators identified by EUPHORIC (including the detailed information collected in the specific indicators sheets). The form was available for the partners in the members' area
- all the information collected during the survey was put on the database by ISS. All the partners were requested to validate and, if necessary, update it under their responsibility. Afterwards, all the information related to indicators was published in the public area
- as technical support for all the partners, ISS prepared and sent them a guideline to correctly input the indicators data on the database (Deliverable 11). The definition of the protocol to validate all the records (by the administrator, ISS - project coordinator) is now operative
- a search engine was developed on the questionnaire database to help users make advanced searches on the questionnaire web-based database.

Involvement of partners and target groups

The main beneficiary regarding: the design of the website, the contents definition, and the input of the information collected during the survey and already available in the first deliverable. The technical partner, CASPUR for the implementation. All the partners for their own pages. Partners ISS, IMAS-IMIM, STAKES, KI, NKUA, DEASL, EAR, NCPHP validated the collected information.

Information about the countries and the health systems of the participating countries, except France because partner SOFCOT didn't provide it, were uploaded onto the website. The

collaborating partners included in the project after 2006 were not requested to collect information about indicators in their countries for two main reasons: 1) they did not participate in the survey phase (2004-2006); 2) they were included in order to cooperate in the development of the pilot and to support the dissemination and they did not receive any budget to invest in this extra activity.

Coordination with other projects or activities

None.

Outcomes and deliverables achieved

- first beta version of the website online in March 2007
- final version of the website online in September 2008
- setting up of the electronic form. Input of the already collected data. Validation of the questionnaires by all the partners. Organization of the members' area
- preparation of the guideline to correctly input the indicators data on the database (Deliverable n.11)
- report prepared by MEDISOFT, "The EUPHORIC Web Application and Data Recovery System - Creation of a web service for data "consumption"" (Annex 5).

Problems encountered

The difficulty in formalizing the contract with the technological partner (CASPUR) before receiving the advance payment delayed the start of the development of the website.

Partner EAR-EFORT was officially included in the project on 26 January 2007 when the survey had already been concluded. The organization of the pilot and the delay in receiving the payments prevented them from hiring a person responsible for collecting all the information requested during the survey.

On the basis of the new organization of the project (based on the testing of indicators on data extracted from existing databases at specified dates), it seemed useless to implement a system that gathers data on a real time basis. Nevertheless, this kind of approach might be useful for the development of possible future projects requiring this kind of technology whose application, at present, is beyond the defined EUPHORIC objectives.

How problems were resolved

Receipt of the payment in June 2006.

Start of the contract with CASPUR in September 2006

Partner EAR-EFORT integrated and updated the information about data sources and databases available in Austria during 2008. ISS supported them from a technical point of view.

All other partners were requested to check and validate the indicators already put on the database and to integrate the missing records.

The MEDISOFT product was considered as a feasibility study. A report summarizing the activity was prepared (Annex 5). However, since it was impossible to implement this activity in the EUPHORIC context, the contract was interrupted in 2007 and the changes in the budget were considered in the submitted amendment.

4. CONCLUSIONS AND RECOMMENDATIONS

After a difficult start and several administrative problems preventing its regular development, EUPHORIC was able to achieve the stated objectives thanks to the efforts of the consortium, especially of the project's and pilots' leaders. Establishing a high quality framework consortium is a key issue for success. In EUPHORIC, most of the initial work involved introducing each partner and understanding how each partner should contribute. In the light of the EUPHORIC experience, starting a project with a "core group" that has an accepted and consolidated, fruitful cooperation but is also interested in widening and networking their knowledge with other potential partners might accelerate the initial phases of the project's development. Moreover, in order to optimize the project's available time frame, tasks to be carried out by each partner should be defined beforehand. Signing a mutual consortium agreement could be useful in formalizing cooperation and could help the project leader in managing a very critical issue which is the preparation of the planned documents and the respect of the stated deadlines. Furthermore, the consortium should consider all the interested stakeholders and not be limited to the "scientific" community. Having the possibility of sharing different points of view might give the achieved results a higher added value. The aim of an action in the public health field is to improve the quality of the provided health care and, therefore, the quality of life of the patients involved who are ultimately the real target. Therefore, since patient associations play a very important role in this sense, they should be considered in the network from the beginning of the project in order to involve all the concerned parties. Unfortunately, cooperation between EUPHORIC and the European Patients' Forum representatives was limited to the last year of activity and then it was possible to cooperate only in the implementation of the dissemination. However, very useful input was given, especially to the contribution to the virtual table of discussion. Previous cooperation would have helped in the definition and selection of the indicators that also take into account quality of life measurements.

The aim of the first phase of the project, the survey, was to define a list of outcome indicators and to collect information about the sources of data available in the participating countries in order to compute the indicators included in the list. On the basis of the data available in the first year of activity, i.e. in 2005, EUPHORIC defined a list of 54 outcome indicators in nine areas of disease and integrated the work carried out in other projects, such as ECHIM. Concerning this last issue, the definition of the AMI 30-day in-hospital case-fatality rate given by EUPHORIC was successively included in the ECHIM short list. For each health outcome indicator, detailed information was collected and also uploaded in a searchable database available on the project website. The information related to the sources available in the participating countries was organized in a web-based database. This data collection offered the opportunity to the whole consortium to exchange information on quality standards, best practice and effectiveness in public health systems of the participant countries. The list of indicators, the selected areas of disease and the description of the data sources available were essential for the further design of the pilot. However, if used now, it must be taken into account that they would need to be updated and this is especially true for the indicators. As suggested during the final EUPHORIC workshop by Björn Smedby of the HDP project expert group, a more careful definition of the diagnoses, procedures, coding and registration differences between the countries should also be taken into account if the indicators are calculated using hospital discharge registers. Some preliminary indications for three selected indicators are available in the results achieved in the risk adjustment and statistics pilot (Deliverable n. 12.5 Extended protocols) proposing some modifications in the definitions of the indicators.

The second phase of the project, the pilot, provided interesting results in the cardiovascular and orthopaedic areas and verified the hypothesis that the possibility of developing common

outcome indicators in Europe exists. Efforts were made to identify common European elements suitable for a political European platform oriented at best practice guarantees for European citizens. Standardized methodologies were designed and tools developed to assess the quality of care of some selected health procedures.

The final result of the cardiovascular pilot involved a web-based tool that allows hospitals to confidentially self-benchmark their in-house mortality rate. After some preliminary discussions with DG SANCO, it seems that the tool developed by the cardiovascular pilot is of relevant interest for future projects, in particular for the project EURHOBOP (currently under negotiation with EAHC). It must be stated that the tool developed under EUPHORIC has to be considered a "beta" version and needs to be validated. As a result, the functions of the cardiovascular algorithm are now only available in the restricted area of the EUPHORIC website since they need both a proper validation with real data from a number of hospitals in Europe and also periodic updating with new data. In fact, the rapid advancement of acute coronary syndrome management might lead to outdated benchmarking functions. As well, changes in the social characteristics of a country may change the validity of these functions that rely on data from the first five years of this decade. It was therefore suggested to carry out all the validation related activities in future projects like EURHOBOP. EUPHORIC will carry out all the necessary tasks to bridge the two projects. In particular, cooperation with HOPE (European Hospitals and Healthcare Federation) will be established in order to disseminate the results in both networks.

The orthopaedic pilot enhanced the importance of having registers that are available to carry out outcome measurements especially in the field of arthroplasty. Therefore, it proposed to introduce two specific indicators related to arthroplasty in the indicators list: revision rate and revision burden. Moreover, it provided a characterization scheme to assess the scope, design and results of a register, an overview of the registers currently active in Europe and in other neighbouring countries and a description of the Swedish and Finnish outcome monitoring systems. Based on a detailed analysis of the scientific literature, comparisons were made for some selected devices between the revision rates available from published clinical studies and those published in the annual reports of different registers. Moreover, a proposal was made to consider the use of specific technical measurements aimed at early detection of the failure of an implanted device when clinical studies are carried out to support its introduction on the market. All the relevant technical reports and related results will be made public only after approval by DG SANCO and DG Enterprise of both the adopted methodology and of the achieved results of the performed analyses.

The result of the activities carried out in the risk adjustment pilot was the description of different methodologies related to risk adjustment procedures and the steps to develop risk adjustment models. The collaboration between the cardiovascular and the risk adjustment pilots allowed to define the best risk adjustment methodologies for comparative evaluation of outcomes. Moreover, it was possible to select the cardiovascular indicators that are computable on data coming from administrative information systems including, if possible, data from the Emergency Information System or from clinical records. Direct standardization procedures using the entire population under study or the best performing hospitals (benchmark) as a reference were considered the best possible choices.

Routinely collected data, such as hospital discharge records, are an invaluable source of information, therefore, particular attention was paid to investigate their validity for all the areas concerned by the pilot. The limits of administrative databases were highlighted: although they clearly offer advantages in comparative evaluation of outcomes, being relatively inexpensive and generally covering a large population, they also have important drawbacks from a clinical perspective, that is a limitation of ICD coding and absence of many important clinical variables. The risk adjustment and statistics pilot started exploring the possibility of collecting information from administrative and clinical databases in order to identify the most important factors to be included in the risk adjustment models. However, further analyses are still necessary and the

development of other standardized, more complex statistical procedures for the comparative evaluation of outcomes, in particular Multilevel Modelling and Bayesian Analysis are recommended.

In conclusion, even if its interests were focussed on some selected procedures, EUPHORIC might be considered the initial spark to make policy makers and all the interested stakeholders aware that the implementation of systematic outcome assessment throughout all European member states might be possible and further investments should be sustained. In particular, EUPHORIC enhanced the important aspect that it is possible for hospitals to confidentially self-benchmark their in-house mortality rate when managing acute myocardial infarction, thereby triggering a process of improvement of provided health care with a direct benefit for the patients.

The EUPHORIC initial structure considered dissemination as the third and last phase of the project. However, based on our experience, we can state that it is basically wrong to consider it the last activity and to implement it only when results are available. In fact, dissemination should be considered a key action in the development of each project. Thus, a suitable dissemination strategy that allows to target the widest audience must be defined at the beginning of the project by planning the design and definition of all the most appropriate tools. This is even more important for projects related to the public health field when not only scientists but also patients and citizens are interested in the results achieved. To provide the most suitable information to all the targeted stakeholders, cooperation with people specialized in communication strategy should be considered when dissemination is organized. For EUPHORIC, the close cooperation initiated by the main beneficiary with the scientific publisher Zadig in the spring of 2008 gave a boost to the dissemination activities allowing the project to achieve additional objectives not originally defined. Since then, it was possible to develop some specific documents that have been useful in supporting the dissemination, namely: a newsletter that circulated in the networks of the participating institutions informing about the progress of the project; a brochure translated in the 11 languages spoken in the participating countries; a video giving an overview of the project showing the relevance of outcome research for the continuous improvement of the care provided by health systems; and a virtual table of discussion involving scientists, patient associations and citizens and aimed at presenting different opinions about the publication of the data resulting from the use of outcome indicators (for example, in benchmarking hospitals). All these items will be downloadable from the project website after approval by the Commission. A model of the press release will be delivered to the Commission after approval of the report.

5. ANNEXES

Annex 1 Logo of the EUPHORIC Project

Annex 2 Abstract presented at the 15th EUPHA Conference

Annex 3 Abstract presented at the 16th EUPHA Conference

Annex 4 Contribution by the EUPHORIC project to the EUGLOREH project: The Status of Health in the European Union: towards a Healthier Europe

Annex 5 Report "The EUPHORIC Web Application and Data Recovery System - Creation of a web service for data “consumption”" by MEDISOFT

6. DELIVERABLES

Deliverable n. 1	Survey: the first phase of the project	Dec 08	Rel.3
Deliverable n. 2	Glossary	Jul 08	Rel.2
Deliverable n. 3	Evaluation Plan	Feb 09	Rel.2
Deliverable n. 4	Indicators submitted to ECHIM to be considered in the short list	Nov 07	Rel.1
Deliverable n. 5	Dissemination Plan	Mar 09	Rel.2
Deliverable n. 6	Detailed sheets of the collected outcome indicators (long list)	Dec 08	Rel.2
Deliverable n. 7	Platelet glycoprotein IIb/IIIa blockers for percutaneous coronary intervention, and as initial treatment in Non-ST segment elevation Acute Coronary Syndromes. (Systematic review of the literature)	Nov 07	Rel.1
Deliverable n. 8	Protocol for the Cardiovascular Pilot Study	Jun 08	Rel.2
Deliverable n. 8.1	Cardiovascular Pilot Study – Final technical report	Feb 09	Rel.1
Deliverable n. 9	Protocol for the Orthopaedic Pilot Study	Sep 07	Rel.1
Deliverable n. 9.1	Orthopaedic Pilot Study – Final technical report	Apr 09	Rel.1
Deliverable n. 9.2	Quality Registers in Finland	Mar 09	Rel.1
Deliverable n. 9.3	Quality Registers in Sweden	Feb 09	Rel.1
Deliverable n. 9.4	Characterising Registries for reviewing purposes	Jan 09	Rel.1
Deliverable n. 9.5	Register-based Documentation of Economic and Administrative Data and Linkage to Outcome measurement – Report by the Romanian National Arthroplasty Register	Feb 09	Rel.1
Deliverable n. 9.6	Economic data concerning Arthroplasty and Register data from Emilia Romagna	Dec 08	Rel.1
Deliverable n. 9.7	Potential Use of Discharge Records in Outcome Measurement and Link with Data from Outcome Registers based on the example of Arthroplasty	Feb 09	Rel.1
Deliverable n. 9.8	Data Mining and Arthroplasty Register datasets	Feb 09	Rel.1
Deliverable n. 10	Risk adjustment methodologies	Feb 08	Rel.1
Deliverable n. 11	Web-based Questionnaire: completion guideline	Sep 08	Rel.2
Deliverable n. 12	Protocol for the risk adjustment and statistics workpackage	Jul 08	Rel.1
Deliverable n. 12.1	Information on national hospital data collections in the EU states participating in the EUPHORIC project	Jan 09	Rel.1
Deliverable n. 12.2	Information from cardiovascular and arthroplasty registries	Jan 09	Rel.1
Deliverable n. 12.3	Identifying cardiovascular diseases (CVDs) by using one or more information sources	Jan 09	Rel.1
Deliverable n. 12.4	Identifying the clinical variables determining the difference in terms of comparative evaluation of outcomes between register-based or information system-based risk adjustment models	Jan 09	Rel.1
Deliverable n. 12.5	Extended protocols	Jan 09	Rel.1
Deliverable n. 12.6	Identification and definition of risk factors for comparative evaluation of outcomes - A “change-in” estimate procedure	Jan 09	Rel.1
Deliverable n. 12.7	Statistical procedures for comparative evaluation of outcomes	Jan 09	Rel.1