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# Deliverable N. 8

# Protocol of the EUPHORIC Pilot Study on Cardiovascular diseases

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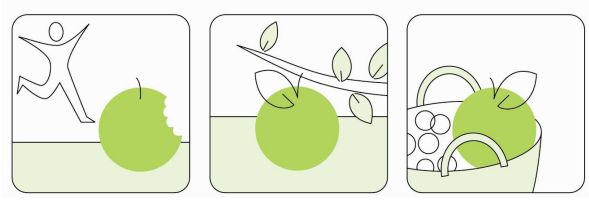

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# Background

Following health provisions introduced in the article 129 (Maastricht Treaty) and then in the article 152 (Amsterdam Treaty) the EU promoted a health strategy which gave rise to the Programme of Community Action in the Field of Public Health (2003-2008).

The Programme, adopted by the European Parliament and Council on 23 September 2002, was defined with the overall aim "to protect human health and improve public health". It includes three strands of action:

- to improve information and knowledge for the development of public health
- to enhance the capability of responding rapidly and in a coordinated fashion to health threats
- to promote health and prevent disease through addressing health determinants across all policies and activities

Funded under the Programme, the EUPHORIC project focuses on the first strand pursued by means of actions and support measures such as "developing and operating a sustainable health monitoring system" to establish comparable quantitative and qualitative indicators at community level on the basis of existing work and of accomplished results A survey will be conducted to make an inventory of the outcome research studies and indicators existing in the participant countries.

From the inventory and from the literature search, a participant forum was completed in 2006 organized to identify the most appropriate conditions and to select the procedures more suitable for the project.

Initially the following conditions were considered: Acute Coronary Syndrome (either with or without electrocardiographic ST Elevation), Heart Failure, Stroke, Valvular disease, or Peripheral artery disease.

It was easy to conclude that acute coronary syndrome (ACS) was the easiest since admission is always required, there are many ongoing registers, and in-hospital and 6-month procedure-use and -outcome are relatively easy to monitor. The considerations that led to this decision were as follows:

We had no personal experience on valvular disease, and the facts that the rates of rheumatic valve disease are decreasing in Europe, the aortic degenerative disease is increasing in elderly patients alone, mortality is low, and the surgical procedures are very standardized, discouraged us from selecting this disease for the pilot study. Similarly we also discarded stroke because we had limited personal experience with this disease, mortality rates were similar to those for ACS and the procedures for acute treatment were less standardized. On top of this, it is classically difficult to classify its aetiology (ischemic, haemorrhagic principally). Finally we also discarded peripheral artery disease owing to our limited personal experience in the disease, its low mortality, the much less standardized procedures for treatment of chronic and acute events and the high morbimortality for other CV diseases (coronary and stroke principally).This disease seldom requires admission for acute events: only programmed surgical interventions are found in discharge records making it difficult to register. Finally we also dismissed heart failure because patients with this condition are admitted in more than one hospital departments and types of hospitals. There are many aetiologies (hypertension, cardio myopathies, coronary heart disease, drugs, alcohol), and there are no standardized diagnosis criteria: as a matter of fact there are currently 3 guidelines with three different sets of criteria. Short-term mortality rates are usually high, and it is difficult to determine severity: left ventricular ejection fraction is the strongest determinant of prognosis. There is very low treatment variability among hospitals.

Patients admitted for an ACS receive a discharge diagnosis of myocardial infarction (MI) either with or without Q-wave in the electrocardiogram, unstable angina, stable angina or non-coronary-ischaemic disease. ACS does not exist as an entry in the international classification of diseases (ICD), which is used in discharge diagnosis in European hospitals. MI is an easy-to-

identify, ICD-clearly-defined condition with a high social impact, whose management includes a number of procedures that suit the objectives of EUPHORIC study due to their availability in many hospitals in Europe and the fact that they are collected in already existing monitoring systems. Particularly we have chosen:

1. Coronary-artery-by-pass-graft (CABG),
2. Coronary angiography,
3. Thrombolysis,
4. Percutaneous intervention (angioplasty with or without stenting),
5. General MI and unstable angina management,
6. GPIIbIIIa blocker use (meta-analysis).

Hospital, country, and individual characteristics are probably at the origin of varying outcome of procedures used in ACS. Therefore, a number of such characteristics have been taken into account in the analyses.

# Objectives of the pilot study on cardiovascular diseases

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 will be analyzed in the context of characteristics at individual, hospital and country levels.
2. To develop a set of tools (mathematical functions) to benchmarking 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 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 the ACS.

# Methods

## First objective

*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 will be analyzed in the context of characteristics at individual, hospital and country levels.*

***Design***

A cohort study will be used. We will use the already collected data of the MASCARA study, which gathered more than 8000 ACS patients followed for 6 months. This data-base will allow examining the role of individual and hospital factors on the occurrence of the events considered in the outcome. Other existing data bases including several countries (e.g., European Heart Survey (EHS) on ACS 2005) may also be used to analyze the country factors if an agreement is reached with the investigators at the European Society of Cardiology to explore the

possibility of using their database of some 6,000 myocardial infarction patients collected in more than 40 European countries in 2005 for an additional individual plus hospital plus country-level analyses. Other acute coronary syndrome registries will be sought and used if appropriate agreements are achieved.

***Patients***

Within ACS, all types of myocardial infarction (MI) –i.e., electrocardiographic Q-wave and non-q-wave-, or unstable angina on discharge will be included in the analysis to seek the set of factors that determine the quality of health care outcome.

We will use recent (later than year 2000 to prevent problems with ancient definitions that excluded troponin values) existing international databases corresponding to myocardial infarction or acute coronary syndrome registries.

***Procedures***

Done during hospitalization for a myocardial infarction or unstable angina: 1) percutaneous revascularization: primary and overall percutaneous intervention (PCI) -including stenting with or without eluting drugs-; 2) thrombolysis use, 3) coronary angiography use, and 4) coronary artery bypass grafting (CABG).

***Outcome***

In-hospital mortality (case-fatality) after the procedure and a combined end-point of in-hospital death, re-infarction or angina post-infarction will be the two outcomes considered in this pilot study. Mortality (case-fatality) represents a hard standardizable end-point that can be easily retrieved from death certificate-based registries in the context of administrative data collection and linkage whenever this information is not collected in administrative discharge records. If possible similar end-points at 6 months will also be considered.

# *INDICATORS*

| General myocardial infarction and unstable angina patient management (EUPHORIC A-9 & A-10) | |
|---|---|
| **Definition** | 30-day mortality (case-fatality) in patients with discharge diagnosis of myocardial infarction |
| **Calculation** | Patients with discharge diagnosis of myocardial infarction or unstable angina who die within 30 days after admission /<br>patients with discharge diagnosis of myocardial infarction or unstable angina regardless of their vital status on discharge |
| **Additional underlying concepts** | 30-day mortality (case-fatality) may be substituted by in-hospital mortality (case-fatality) given the fact that typically, patients are followed up to the discharge time and not 30 days which is a convenience for prospective research |
| **Relevant dimension (subgroups)** | Women are known to have worse outcomes than men after myocardial infarction. Proper adjustment for severity and comorbidity may be required. |
| **Preferred data sources** | Discharge records & hospital registries when existing to update the reference for benchmarking |
| **Rationale** | |
| **Data availability, quality and periodicity** | Usually recorded in administrative/systematic hospital discharge data bases as a diagnosis. Assessment every 5 years recommended. Comorbidity adjustment factors may be missing in administrative data. |
| **References** | Tu JV, et al. Development and validation of the Ontario acute myocardial infarction mortality prediction rules. J Am Coll Cardiol 2001;37:992-7.<br>Bundorf MK, et al. Impact of managed care on the treatment, costs and outcomes of fee-for-service Medicare patients with acute myocardial infarction. Health Serv Res 2004;39:131-52.<br>Núñez JE, et al. [Valor pronóstico del índice de comorbilidad de Charlson a los treinta días y a un año después del infarto agudo de miocardio]. Rev Esp Cardiol 2004;57:842-9.<br>Krumholz HM,et al. An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with an acute myocardial infarction. Circulation 2006;113:1683-92.<br>Sendra Gutiérrez JM, et al. Desarrollo de un modelo de ajuste por el riesgo para el infarto agudo de miocardio en España: comparación con el modelo de Charlson y el modelo ICES. Aplicaciones para medir resultados asistenciales. Rev Esp<br>Salud Pública 2006;80:665-677.<br>Marrugat J, Sanz G, Masià R, Valle V, Molina L, Cardona M, Sala J, Serés L, Szescielinski L, Albert X, Lupón J, Alonso J, for the RESCATE Investigators. Six-month outcome in patients with myocardial infarction initially admitted to tertiary and nontertiary hospitals. J Am Coll Cardiol. 1997; 30: 1187-1192. |
| **Work to do** | |

| Coronary artery bypass grafting (CABG). EUPHORIC A-3 & A-4 | |
|---|---|
| **Definition** | 30-day mortality in patients with discharge diagnosis of myocardial infarction and were submitted to CABG |
| **Calculation** | patients with discharge diagnosis of myocardial infarction who were submitted to CABG and died within 30 days after admission /<br>patients with discharge diagnosis of myocardial infarction who were submitted to CABG regardless of their vital status on discharge |
| **Additional underlying concepts** | |
| **Relevant dimension (subgroups)** | Women are known to have worse outcomes than men after myocardial infarction. Proper adjustment for severity and comorbidity may be required. |
| **Preferred data sources** | Discharge records & hospital registries when existing to update the reference for benchmarking |
| **Rationale** | |
| **Data availability, quality and periodicity** | Usually recorded in administrative/systematic hospital discharge data bases as a procedure. Assessment every 5 years recommended. Comorbidity adjustment factors may be missing in administrative data. |
| **References** | Hannan EL, et al. Coronary artery bypass surgery: the relationship between inhospital mortality rate and surgical volume after controlling for clinical risk factors. Med Care 1991;29:1094-107.<br>Higgins TL, et al. Stratification of morbidity and mortality outcome by preoperative risk factors in coronary artery bypass patients. A clinical severity score. JAMA 1992;267:2344-2348.<br>O'Connor GT, et al. Multivariate prediction of in-hospital mortality associated with coronary artery bypass grafo surgery. Circulation. 1992;85:2110-8.<br>Hannan EL, et al. Improving the outcomes of coronary artery bypass surgery in New York State. JAMA. 1994;271:761-766.<br>Ghali WA, et al. Searching for an improved clinical comorbidity index for use with ICD-9-CM administrative data. J Clin Epidemiol 1996;49:273-8.<br>Plogman PL, et al. Anthem Blue Cross and Blue Shield's coronary services network: a managed care organization's approach to improving the quality of cardiac care for its members. Am J Manag Care 1998;4:1679-86.<br>Ivanov J, et al. Ready-made, recalibrated, or Remodeled? Issues in the use of risk indexes for assessing mortality after coronary artery bypass graft surgery. Circulation 1999;99:2098-104.<br>Shroyer AL, et al. The 1996 coronary artery bypass risk model: the Society of Thoracic Surgeons Adult Cardiac National Database. Ann Thorac Surg 1999;67:1205-8.<br>Charlesworth DC, et al. for The Northern New England Cardiovascular Disease Study Group. Development and validation of a prediction model for strokes after coronary artery bypass grafting. Ann Thorac Surg 2003;76:436-43.<br>Hannan EL, et al. Do hospital and surgeons with higher coronary artery bypass graft surgery volumes still have lower risk-adjusted mortality rates? Circulation. 2003;108:795-801.<br>Likosky DS, et al; Northern New England Cardiovascular Disease Study Group. Intra- and postoperative predictors of stroke alter coronary artery bypass grafting. Ann Thorac Surg 2003;76:428-34.<br>Peterson ED, et al. Procedural volume as a marker of quality for CABG surgery. JAMA 2004;291:195-201.<br>Ugolini C, Nobilio L. Risk adjustment for coronary artery bypass grafo surgery: an administrative approach versus EuroSCORE. Int J Qual Health Care 2004;16:157-64.<br>Cram P,et al. Cardiac revascularization in specialty and general hospitals. N Engl J Med 2005;352:1454-62<br>Ferreira-Gonzalez IJ, et al; ARCA study group. Outcomes in off-pump vs. on-pump coronary artery bypass grafting stratified by pre-operative risk profile: an assessment using propensity score. Eur Heart J 2006;27:2473-80.<br>Novick RJ, et al. Direct comparison of risk-adjusted and non-risk-adjusted CUSUM analyses of coronary artery bypass surgery outcomes. J Thorac Cardiovasc Surg 2006;132:386-391.<br>Selim AJ, et al. Use of risk-adjusted change in health status to assess the performance of integrated service networks in the Veterans Health Administration. Int J Qual Health Care 2006; 18:43-50. |
| **Work to do** | |

| Percutaneous intervention: angioplasty with or without stenting (PCI). EUPHORIC Not foreseen | |
|---|---|
| **Definition** | 30-day mortality (case-fatality) in patients with discharge diagnosis of myocardial infarction or unstable angina and were submitted to PCI |
| **Calculation** | patients with discharge diagnosis of myocardial infarction or unstable angina who were submitted to PCI and died within 30 days after admission / patients with discharge diagnosis of myocardial infarction or unstable angina who were submitted to PCI regardless of their vital status on discharge |
| **Additional underlying concepts** | 30-day mortality (case-fatality) may be substituted by in-hospital mortality (case-fatality) given the fact that typically, patients are followed up to the discharge time and not 30 days which is a convenience for prospective research |
| **Relevant dimanesion (subgroups)** | Women are known to have worse outcomes than men after myocardial infarction. Proper adjustment for severity and comorbidity may be required. |
| **Preferred data sources** | Discharge records & hospital registries when existing to update the reference for benchmarking |
| **Rationale** | |
| **Data availability, quality and periodicity** | Usually recorded in administrative/systematic hospital discharge data bases as a procedure. Assessment every 5 years recommended. Comorbidity adjustment factors may be missing in administrative data. |
| **References** | Hannan EL, et al. Percutaneous transluminal coronary angioplasty in New York State. Risk factors and outcomes. JAMA 1992;268: 3092-7.<br>Hannan EL,et al. Coronary angioplasty volume-outcome relationships for hospitals and cardiologists. JAMA. 1997;279:892-8.<br>Ellis SG, et al. Relation of operator volume and experience to procedural outcome of percutaneous coronary revascularization at hospitals with high interventional volumes. Circulation 1997;95:2479-84<br>O'Connor GT, for the Northern New England Cardiovascular Disease Study Group. Multivariate prediction of in-hospital mortality after percutaneous coronary interventions in 1994-1996. J Am Coll Cardiol 1999;34:681-91<br>Moscucci M, et al for the Blue Cross Blue Shield of Michigan Cardiovascular Consortium. Simple bedside additive tool for prediction of in-hospital mortality after percutaneous coronary interventions. Circulation. 2001;104:263-8<br>Shaw RE, et al Development of a risk adjustment mortality model using the American College of Cardiology- National Cardiovascular Data Registry (ACC-NCDR) experience: 1998-2000. J Am Coll Cardiol 2002;39:1104-12.<br>Piper WD, et al for The Northern New England Cardiovascular Disease Study Group. Predicting vascular complications in percutaneous coronary interventions. Am Heart J 2003;145:1022-9.<br>Moscucci M, et al. Public reporting and case selection for percutaneous coronary interventions: an analysis from two large multicenter percutaneous coronary intervention databases. J Am Coll Cardiol 2005;45:1759-65. |
| **Work to do** | |

| Thrombolysis. | |
|---|---|
| **Definition** | 30-day mortality (case-fatality) in patients with discharge diagnosis of myocardial infarction and were submitted to thrombolysis |
| **Calculation** | patients with discharge diagnosis of myocardial infarction who were submitted to thrombolysis and died within 30 days after admission / patients with discharge diagnosis of myocardial infarction who were submitted to thrombolysis regardless of their vital status on discharge |
| **Additional underlying concepts** | 30-day mortality (case-fatality) may be substituted by in-hospital mortality (case-fatality) given the fact that typically, patients are followed up to the discharge time and not 30 days which is a convenience for prospective research |
| **Relevant dimension (subgroups)** | Women are known to have worse outcomes than men after myocardial infarction. Proper adjustment for severity and comorbidity may be required. |
| **Preferred data sources** | Hospital registries when existing to update the reference for benchmarking. Usually not collected in discharge administrative records. |
| **Rationale** | This a secondary indicator that may be difficult to implement |
| **Data availability, quality and periodicity** | Rarely recorded in administrative/systematic hospital discharge data bases |
| **References** | |
| **Work to do** | |

| Percutaneous transluminal coronary angiography (PTCA). EUPHORIC A-5 & A-6 | |
|---|---|
| **Definition** | 30-day mortality (case-fatality) in patients with discharge diagnosis of myocardial infarction or unstable angina and were submitted to PTCA |
| **Calculation** | patients with discharge diagnosis of myocardial infarction or unstable angina who were submitted to PTCA and died within 30 days after admission / patients with discharge diagnosis of myocardial infarction or unstable angina who were submitted to PTCA regardless of their vital status on discharge |
| **Additional underlying concepts** | 30-day mortality (case-fatality) may be substituted by in-hospital mortality (case-fatality) given the fact that typically, patients are followed up to the discharge time and not 30 days which is a convenience for prospective research |
| **Relevant dimanesion (subgroups)** | |
| **Preferred data sources** | Discharge records & hospital registries when existing to update the reference for benchmarking |
| **Rationale** | |
| **Data availability, quality and periodicity** | |
| **References** | |
| **Work to do** | |

## Second objective

*To develop a set of tools (mathematical functions) to benchmarking 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).*

***Benchmarking hospitals***

Real-life data from existing population-based registries will be used to validate the former. The comparison will be established in terms of procedure-use and outcome rate risk by procedure benchmarking (interquartile and $5^{th}$ and $95^{th}$ percentiles of the expected ranking will be provided anonymously to the assessed Hospital according to its patient and structural characteristics taking into account the country characteristics that are found to be also determinants of outcome).

***Statistical analyses***

For each procedure (CABG, thrombolysis, coronary angiography and coronary angioplasty) and selected outcome (in-hospital mortality (case-fatality), and in-hospital death or re-infarction or a new episode of myocardial ischaemia) three types of multivariate models adjusting for sex, age, severity of myocardial infarction and comorbidity will be fit: first including hospital as a fixed effect and comparing each hospital rate with the average rate, and second adding to the former the variable "hospital" as a random effect but extending the model with characteristics at the hospital level (i.e. number of beds, catheter laboratory existence, etc.) as fixed effects. Eventually models further extended with country characteristics (e.g., life expectancy, cardiovascular mortality etc…) also as fixed effects will be considered if the EHS-ACS can be analyzed.

The former models will allow benchmarking hospitals regardless of their characteristics. The second approach will allow us to benchmark hospitals taking into account their characteristics. Finally, the third approach will permit also to take into account the country characteristics if they are found to be relevant to outcome.

We will determine which of the potential confounders at Individual and Hospital level (and eventually at country level also if the EHS-ACS can be analyzed) with a multilevel general multiple linear regression model.

Several models will be fit with increasing complexity in the number of variables, in such a way that all the country administrative discharge data can be used regardless of their completeness for benchmarking hospitals.

Analysis will be done fitting a logistic model in a Bayes methodology. For each fixed effect we can obtain an estimate of risk. For random effect (i.e. hospital) we will obtain residuals where a positive value means an excess risk, and, conversely with a negative value. The 95% lokely interval will be calculated for each estimate.

***Confidentiality***

In all databases patients identity will be concealed in anonymous consecutive number identification, and hospitals will be assigned a code by the partners. The benchmarking will be done with these codes. Hospitals will be informed of their own code but not those of the rest of hospitals. Whenever a participant or a hospital could be identified given a particular context (e.g. very few participating hospitals with very different characteristics from a country which might make them easily identifiable).

***Ethics***

All participants in MASCARA (Spain) and EHS-ACS (40 countries) were either asked to provide a signed consent or be fully anonymous and the studies will have to have been approved by at least one ethics committee in each participant country.

## Third objective

*To test the functions that estimate the indicators to information obtained routinely for administrative purposes.*

In the phase we will apply this set of functions to the administrative discharge databases provided by the participating countries. A hospital benchmarking tool will be then set up in the EUPHORIC web site.

***The country level candidate basic characteristics***

The country level characteristics can be taken from existing data bases (e.g., EU ISARE project at http://www.isare.org/, HCQIM (OECD Health Care Quality Indicators Project). www.oecd.org, ECHIM (European Community Health Indicators Monitoring) www.echim.org, http://www.healthindicators.org/ICHI/general/startmenu.aspx, WHO, etc...) but also requested to the partners for validity assessment. This list is a desideratum and may be shortened if we find out that it cannot be obtained in full for most countries.

***The candidate Hospital-level characteristics***

Partners will be asked to provide the following information:

1. Hospital code (to match that provided with the data below)
2. Total number of acute hospitalization beds
3. Intensive Care Unit alone, Coronary care unit, Both, None (ICU=1, CCU= 2, Both=3 or none=0)
4. Catheter laboratory existence (0=No; 1=Yes)
5. Cardiovascular Surgery Department existence (0=No; 1=Yes)
6. University Hospital (0=No; 1=Yes)

***The administrative discharge /admission data***

To benchmark a particular hospital it will need the proportion of patients with the characteristics that are chosen in the models among the admitted patients for the disease or procedure whose outcome is evaluated. Each Hospital will have to provide its own characteristics as per the finally chosen. The necessary country data will be taken from the above mentioned data-bases and periodically updated.

***Candidate data from registries***

The following data will be used in the analyses of existing population European acute coronary syndrome registries to select the variables that better determine the fate of patients submitted to the analyzed procedures and diseases management.

1. Patient code (anonymous)
2. Hospital Code
3. Country
4. Age
5. Gender
6. Smoking
7. Hypertension
8. Dyslipaemia
9. Peripheral artery disease
10. Diabetes
11. Family History of CHD
12. Other CVD
13. Previous angina
14. Congestive heart failure
15. Previous revascularization
16. Previous CABG
17. Previous renal failure
18. Previous stroke
19. Time symptom-1st monitorization
20. Time symptom-revascularization
21. Ventricular fibrilation < 24h
22. Ventricular tachicardia < 24h
23. Atrio-ventricular blockade < 24h
24. Atrial fibrillation of flutter < 24h
25. Severe mitral valve dysfunction
26. Admission Killip class
27. Glycaemia mg/dl
28. Total cholesterol mg/dl
29. LDL cholesterol mg/dl
30. HDL cholesterol mg/dl
31. Triglycerides mg/dl
32. Hemoglobin mg/dl
33. Ventricular fibrillation >24h
34. Ventricular tachycardia >24h
35. Atrio-ventricular blockade >24h
36. Atrial fibrillation of flutter >24h
37. Killip class maximal > 24 h
38. Oral Beta Blockers. Discharge
39. Statins. Discharge
40. ACE Inhibitors. Discharge
41. **Coronary angiography**
42. **Thrombolysis**
43. **Revascularization with primary angioplasty.**
44. **Coronary artery bypass surgery**
45. Cardiac death 0-30 days.
46. ReMI 0-30 days.
47. Angina post infarction 0-30 days
48. Cardiac death 30 days-6 months
49. Readmission for ReMI 30 days-6 months.
50. Angina / revascularization 30 days-6months.

## Fourth objective

*To develop and update a systematic review of the literature on the efficacy of GPIIb-IIIa inhibitors in the ACS*

Platelet GPIIbIIIa blocker use is currently an important practice in PTCA procedures: we have deemed necessary to assess its usefuleness in a systematic meta-analysis that will be published in the prestigious Cochrane Library.