

ANNEX I a

(Technical annex)

Title:	Promoting better health for mothers and babies through routine European monitoring of perinatal health and health care (EURO-PERISTAT Action)
Duration (in months)	36
Priority area:	3.4.2 Generate and disseminate health information and knowledge - Collect, analyse and disseminate
Action:	Integrate the perinatal health indicators into public health monitoring systems and prepare its integration into the work of the European statistical system
Sub-action:	**** no sub-action****

Executive summary

The projects ultimate aim is to achieve better health for mothers and babies by building a European perinatal health surveillance system to provide evidence to policy makers, clinicians and users for informed decision-making. We aim to implement a financially sustainable approach to the production and use of perinatal health data in which (1) core EURO-PERISTAT indicators are included in routine statistical systems through EUROSTAT and ECHIM (European Community Health Indicators Monitoring) and (2) a European Network of experts from participating countries is created to monitor other EURO-PERISTAT indicators and to analyse trends and inequalities in health and care for dissemination to target audiences. The project has 5 specific objectives (1) Integrate EURO-PERISTAT perinatal health indicators into European statistical systems (2) Establish a European Perinatal Health Surveillance Network (3) Develop capacity for high quality health reporting (4) Monitor trends and inequalities in perinatal outcomes and care in Europe (5) Expand EURO-PERISTATs geographical coverage.

Strategic relevance & contribution to the programme

This project addresses the third objective of the Health programme “to generate and disseminate health information and knowledge”. All the priorities of 3.2.1 are covered by our aims (Integrate the perinatal health indicators into public health monitoring systems, develop capacity at the European level and at national levels in order to achieve high level reporting) It contributes to other work plan priorities by:

- Monitoring social and geographical inequalities in maternal-child health
- Building capacity for development and implementation of effective public health policies
- Exchanging knowledge and best practices among public health professionals;
- Engaging third countries, through outreach to applicant/candidate countries and exchange of information with researchers in the US, Canada and Australia.

Methods and means

METHODS: The project is based on the EURO-PERISTAT indicators, which were developed with rigorous scientific methods and tested twice (on 2000 and 2004 data). It mobilises the expertise and resources of EURO-PERISTAT's network of clinicians, epidemiologists and statisticians. It will:

- Establish working groups to execute WP objectives, including a technical working group with representatives from EUROSTAT and ECHIM, a network of legal officers, and thematic working groups on data quality, indicator development and social inequalities.
- Consult with external experts (legal specialists; authorities in perinatal health);
- Implement DELPHI consensus processes with the Scientific Committee (one representative per participating country) to update indicators and achieve agreement on the Surveillance Network's charter;
- Compile and analyse data to pretest quality improvement methods and to monitor indicators;
- Expand our existing contact base of over 500 perinatal health decision-makers and develop outreach to

professional and user groups.

Expected outcomes

OUTCOMES: The principal outcome will be a high quality, innovative, internationally recognised and sustainable European perinatal health information system that compiles and analyses data on a regular basis. While transitioning to this system, the project will compile new data and produce analyses on patterns of perinatal health and care in Europe. These are eagerly awaited by perinatal health professionals who wish to monitor the wide inter-country variations in outcomes and care practices revealed by the first European Perinatal Health Report. By improving indicator quality and breadth and using data for scientific analysis, this project maintains the dynamism and relevance of routine reporting and the interest and involvement of our partners and stakeholders. Project deliverables, including a second European Perinatal Health Report on 2010 data, will be broadly disseminated through directed outreach activities and an integrated media strategy.

General objective of the project

The project's ultimate aim is to achieve better health for mothers and babies by building a European perinatal health surveillance system that provides evidence to policy makers, clinicians and users for informed decision-making. We aim to add maximum value to European and national investments in indicator development by implementing a financially sustainable approach to the production and use of perinatal health data. The project is based on the EURO-PERISTAT indicators, which were developed with rigorous scientific methods and tested twice (on 2000 and 2004 data)[6,8]. This project strives to develop a system that produces high quality data, achieves complete geographic representation, responds to the needs of our target groups, is reactive to new health concerns and contributes significantly to national, European and international debates on best care practices for mothers and babies.

Specific objective(s) of the project

#	Title	Description
1	Integrate the EURO-PERISTAT perinatal health indicators into routine European statistical and public health monitoring systems	To establish the legal and technical rules for a permanent European system in collaboration with EUROSTAT, ECHIM Joint Action and the EURO-PERISTAT Scientific Committee. We will identify indicators and establish institutional procedures.
2	Establish an institutional framework and charter for a European Perinatal Health Surveillance Network including clinicians, data providers, and health researchers to monitor and report on perinatal health by using EURO-PERISTAT indicators	To identify a legal and institutional framework and a governance structure, various models will be assessed in collaboration with DG-SANCO, EUROSTAT and legal representatives from institutions participating in EURO-PERISTAT.
3	Develop capacity at the European and national levels in order to achieve high quality health reporting for mothers and babies by improving and harmonising data collection and reporting	Update indicators, create methods for measuring severe maternal morbidity, develop guidelines for data management (birth and death registration, missing data, linkage) and expand methods for measuring social inequalities in perinatal outcome and care.
4	Monitor trends and inequalities in perinatal outcomes and care in Europe and provide data needed to promote evidence-based obstetric and neonatal care and policies	Produce data on perinatal health indicators for the year 2010 and analyse the variation and evolution of health and health care in and between EU MS and other participating countries for 2010. This work will be coordinated with EUROSTAT and ECHIM.
5	Expand the geographic implementation of the EURO-PERISTAT indicators	This objective applies primarily to Bulgaria and Romania, but applicant and candidate countries will be invited to participate. We will identify a scientific committee representative for each country and assess availability and quality of indicators.

Deliverables

Deliverables identified in the following table shall be submitted to EAHC, within two months of the delivery month for the technical and final reports and within one month of the delivery month for all other deliverables

#	Title	Description	Confidentiality level	Month of delivery
1	Report for integration of indicators into ECHIM and EUROSTAT	Report on the legal and technical basis for integrating EURO-PERISTAT indicators into ECHIM and EUROSTAT, including descriptions of the proposed institutional management strategy and the contact point for each MS (Month 12 & 30)	Public	30
2	Established European perinatal health information system	High quality, innovative and internationally recognised information system on European perinatal health, with legal existence and clear governance/functioning rules endorsed by participating countries	Public	30
3	Updated indicators list	An updated EURO-PERISTAT indicator list, revised to reflect changing priorities and health trends for the period 2010-2015	Public	9
4	Endorsed quality criteria	Endorsed quality criteria and guidelines for improving perinatal health statistics, including guidelines for producing indicators of maternal morbidity from hospital discharge data in Europe	Public	12
5	Dataset	A dataset including all core and recommended perinatal health indicators in at least 27 EU member states and Norway for the year 2010	Public	24
6	European Perinatal Health Report (EPHR) on 2010 data	A European Perinatal Health Report (EPHR) monitoring trends and inequalities in perinatal health and care in the EU over the past decade	Public	30
7	Project website, including promotional leaflet	A website featuring customised downloadable tables on perinatal health indicators for 2010 and other project documents (contact information, promotional leaflet, interpretive reports and a laymen's version of the project report).	Public	8
8	Scientific publications	Scientific publications (at least 6, starting in Month 14) on perinatal health and care in Europe, of which at least 2 will focus on geographic and social inequalities	Public	36
9	Evaluation reports and report on the web-based evaluation	a) Two Evaluation reports by an independent panel of policy makers, clinicians and health researchers (M12 & 24) b) Results of a web survey of stakeholders evaluating the EPHR (M34) NOTE: Web survey results are public, evaluations are confidential.	Public	34

Interim and final 10 report and minutes of meetings	Interim and Final reports to the Commission including minutes of Executive Board (Months 1,9,21,36) and Steering Committee meetings (Months 9,36). Note: Minutes & Report annexes are confidential, reports are public.	Public	36
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OVERVIEW - Work Packages and deliverables

#	Title	Leader	Start	End	Deliverables	Global Cost	Staff
1	Coordination of the project	INSERM	1	36	Interim and final report and minutes of meetings	117 396,00 €	287
2	Dissemination of the project	INSERM	1	36	Project website, including promotional leaflet	123 300,00 €	314
3	Evaluation of the project	ULB	1	36	Evaluation reports and report on the web-based evaluation	103 550,00 €	239
4	LEGAL STRUCTURE FOR ROUTINE REPORTING AND INDICATOR INTEGRATION INTO ECHIM AND EUROSTAT	THL	1	36	Report for integration of indicators into ECHIM and EUROSTAT Established European perinatal health information system	143 900,00 €	411
5	IMPROVE CAPACITY FOR HIGH QUALITY COMPREHENSIVE REPORTING AND EXPAND GEOGRAPHIC SCOPE	INSERM	1	36	Updated indicators list Endorsed quality criteria Scientific publications	220 400,00 €	591
6	MONITOR TRENDS AND INEQUALITIES IN PERINATAL OUTCOMES AND CARE IN EUROPEAN MS	TNO	1	36	Dataset European Perinatal Health Report (EPHR) on 2010 data	304 403,00 €	728
Total						1 012 949,00 €	2 570

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Horizontal Work Packages

Work package # 1
Work package title Coordination of the project
Work package description Actions undertaken to manage the project and to make sure that it is implemented as planned
Work package Leader INSERM

List of the partners involved

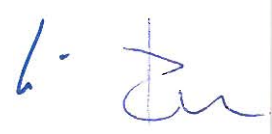
All associated partners

List of deliverable(s) linked to this work package

Deliverable #	Deliverable title
10	Interim and final report and minutes of meetings

Milestones reached by this work package

#	Milestone title	Month of achievement
1	Intermediate and technical reports (Month 12, 24, 36)	36
2	Executive Board meeting N°1 (via webconference)	1
3	Scientific Committee Meeting N°1 & Exeutive Board meeting N°2	9
4	Scientific Committee Meeting N°2 & Exeutive Board meeting N°3	21
5	Exeutive Board meeting N°4 (via webconference)	36



Work package # 2
Work package title Dissemination of the project
Work package description Actions undertaken to ensure that the results and deliverables of the project will be made available to the target groups
Work package Leader INSERM

List of the partners involved

All associated partners All collaborating partners

Overview table showing the distribution and target for all project deliverables

#	Title	Distribution Channel	Target Audience
1	Report for integration of indicators into ECHIM and EUROSTAT	Direct mailing/emails to influentials and decision-makers	Government decision-makers, statistical offices, European statistical offices.
2	Established European perinatal health information system	Direct mailing/emails to influentials and decision-makers, website, outreach to key stakeholders	Government decision-makers, statistical offices, European statistical offices, research institutes in Europe, scientific and professional societies.
3	Updated indicators list	Website, scientific publications, individual outreach to key stakeholders	Clinicians, European and national policy-makers, statistical providers, researchers, users
4	Endorsed quality criteria	Website, scientific publications, direct mailing/emails to key stakeholders.	statistical data providers, European and national policy makers in health surveillance, researchers
5	Dataset	tables will be made available on the website and in the report	Clinicians, European and national policy-makers, statistical providers, researchers, users
6	European Perinatal Health Report (EPHR) on 2010 data	Direct mailing/emails to key stakeholders, Website (free download), Media strategy to ensure articles and other media exposure in the popular press, editorials in scientific journals.	Clinicians, European and national policy-makers, statistical providers, researchers, users and media
7	Project website, including promotional leaflet	Media outreach, links from websites from participating and collaborating institutions.	Clinicians, European and national policy-makers, statistical providers, researchers, users and media
8	Scientific publications	National and international scientific journals	Clinicians, European and national policy-makers, statistical providers, researchers, users
9	Evaluation reports and report on the web-based evaluation	direct mailing/emails to targeted audience. Password protected access from website	Members of the EURO-PERISTAT scientific committee, European evaluators.

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Interim and final
10 report and minutes of meetings

Commission websites

Members of the Europeristat
Scientific Community, European and
national policy makers

List of deliverable(s) linked to this work package

Deliverable #	Deliverable title
7	Project website, including promotional leaflet

Milestones reached by this work package

#	Milestone title	Month of achievement
1	Updated website is launched	8
2	List of stakeholders is updated	12
3	Dissemination plan is set up	12
4	Website includes data from 2010	24

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Work package # 3
Work package title Evaluation of the project
Work package description Actions undertaken to verify if the project is being implemented as planned and reaches the objectives
Work package Leader ULB

List of the partners involved

All associated partners

List of specific objectives

Specific objective 1 Integrate the EURO-PERISTAT perinatal health indicators into routine European statistical and public health monitoring systems

Process Indicators	Output Indicators	Outcomes Indicators
Technical working group meetings including EURO-PERISTAT, ECHIM Joint Action and EUROSTAT members (at least 2 face-to-face meetings)	List of at least 10 indicators agreed upon by EU MS and EUROSTAT for integration into EUROSTAT	Agreement on a strategy with EUROSTAT and EU MS for inclusion of selected perinatal health indicators in routine systems.

Specific objective 2 Establish an institutional framework and charter for a European Perinatal Health Surveillance Network including clinicians, data providers, and health researchers to monitor and report on perinatal health by using EURO-PERISTAT indicators

Process Indicators	Output Indicators	Outcomes Indicators
A report from a DELPHI consensus process on the organization of this network and its members	Document laying out the charter and institutional and financial framework for the network	Creation of a European Perinatal Health Surveillance Network.

Specific objective 3 Develop capacity at the European and national levels in order to achieve high quality health reporting for mothers and babies by improving and harmonising data collection and reporting

Process Indicators	Output Indicators	Outcomes Indicators
Scientific exchange between experts in 2 data workshops	Data on severe maternal morbidity collected using a common protocol in at least 7 countries	Implementation of guidelines for improving quality in data collection

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Specific objective 4

Monitor trends and inequalities in perinatal outcomes and care in Europe and provide data needed to promote evidence-based obstetric and neonatal care and policies

Process Indicators	Output Indicators	Outcomes Indicators
Modification of data collection instrument allowing internet transmission of data	Data on EURO-PERISTAT indicators from participating countries.	Analysis of trends and inequalities in perinatal outcomes and care in Europe disseminated through scientific articles and media

Specific objective 5

Expand the geographic implementation of the EURO-PERISTAT indicators

Process Indicators	Output Indicators	Outcomes Indicators
Representation of new MS on the EURO-PERISTAT scientific committee as measured by participation in both SC meetings.	Data on EURO-PERISTAT indicators from new MS(as measured by tables in European Perinatal Health Report and on the project website)	Full participation of new MS in EURO-PERSTAT project

List of deliverable(s) linked to this work package

Deliverable #	Deliverable title
9	Evaluation reports and report on the web-based evaluation

Milestones reached by this work package

#	Milestone title	Month of achievement
1	Evaluation plan is elaborated	1
2	Panel for Evaluation is identified	6
3	Evaluators participate in Steering Committee meeting (months 9 and 21)	21
4	First and Second evaluation report are ready (months 13 and 24)	24
5	Results of the web survey are obtained	34

Work package #	4
Work package title	LEGAL STRUCTURE FOR ROUTINE REPORTING AND INDICATOR INTEGRATION INTO ECHIM AND EUROSTAT
Work package description	The aim is to create permanent legal and institutional structures for European surveillance of perinatal health by (1) integrating indicators into EUROSTAT and ECHIM and (2) developing a Surveillance Network to analyse and report on data from European and national sources.
Work package Leader	THL

List of the acronyms of associated partners involved

All associated partners All collaborating partners

Specific objectives of this work package

Specific Objective #	Specific objective title
1	Integrate the EURO-PERISTAT perinatal health indicators into routine European statistical and public health monitoring systems
2	Establish an institutional framework and charter for a European Perinatal Health Surveillance Network including clinicians, data providers, and health researchers to monitor and report on perinatal health by using EURO-PERISTAT indicators

List of deliverable(s) linked to this work package

Deliverable #	Outcomes / Deliverable title
1	Report for integration of indicators into ECHIM and EUROSTAT
2	Established European perinatal health information system

Milestones reached by this work package

#	Milestone title	Month of achievement
1	Technical working group established	3
2	Review of indicators and first draft of country reports complete	12
3	Delphi on governance of surveillance network complete	12
4	Report specifying legal options from external advice and Legal officers network	18
5	Final report of working group is completed	30

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Work package #	5
Work package title	IMPROVE CAPACITY FOR HIGH QUALITY COMPREHENSIVE REPORTING AND EXPAND GEOGRAPHIC SCOPE
Work package description	This WP aims to improve structural capacity for producing comprehensive high quality data on the national and European levels. It develops quality guidelines and pretests them on data from sub-sets of countries. This WP also includes activities to expand the geographic scope of the project.
Work package Leader	INSERM

List of the acronyms of associated partners involved

All associated partners All collaborating partners

Specific objectives of this work package

Specific Objective #	Specific objective title
3	Develop capacity at the European and national levels in order to achieve high quality health reporting for mothers and babies by improving and harmonising data collection and reporting
5	Expand the geographic implementation of the EURO-PERISTAT indicators

List of deliverable(s) linked to this work package

Deliverable #	Outcomes / Deliverable title
3	Updated indicators list
4	Endorsed quality criteria
8	Scientific publications

Milestones reached by this work package

#	Milestone title	Month of achievement
1	Protocols for data quality and maternal morbidity analyses established	3
2	New members identified for Scientific Committee	6
3	Workshops on data quality (M 9 and 21 - at SC meetings)	9
4	Endorsement of quality guidelines (at M12 and M24)	12
5	Scientific publications	36

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Work package #	6
Work package title	MONITOR TRENDS AND INEQUALITIES IN PERINATAL OUTCOMES AND CARE IN EUROPEAN MS
Work package description	This WP compiles, analyses and reports on up-to-date data on perinatal health and care using EURO-PERISTAT indicators. As part of the transition to a permanent system, these activities include an interface with those in WP4 and build on the results of quality improvement analyses in WP5.
Work package Leader	TNO

List of the acronyms of associated partners involved

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Specific objectives of this work package

Specific Objective #	Specific objective title
4	Monitor trends and inequalities in perinatal outcomes and care in Europe and provide data needed to promote evidence-based obstetric and neonatal care and policies

List of deliverable(s) linked to this work package

Deliverable #	Outcomes / Deliverable title
5	Dataset
6	European Perinatal Health Report (EPHR) on 2010 data

Milestones reached by this work package

#	Milestone title	Month of achievement
1	Data collection instrument and transmission system modified (software compatible with EuroStat and Echim)	12
2	Data collection complete	18
3	Data validation complete	20
4	Data base ready for integration in website	24
5	European Perinatal Health Report	30

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Timetable specification

	WP 1	WP 2	WP 3	WP 4	WP 5	WP 6
M 1	M	X	M	X	X	X
M 2	X	X	X	X	X	X
M 3	X	X	X	M	M	X
M 4	X	X	X	X	X	X
M 5	X	X	X	X	X	X
M 6	X	X	M	X	M	X
M 7	X	X	X	X	X	X
M 8	X	M/D	X	X	X	X
M 9	M	X	X	X	M/D	X
M 10	X	X	X	X	X	X
M 11	X	X	X	X	X	X
M 12	X	M	X	M	M/D	M
M 13	X	X	X	X	X	X
M 14	X	X	X	X	X	X
M 15	X	X	X	X	X	X
M 16	X	X	X	X	X	X
M 17	X	X	X	X	X	X
M 18	X	X	X	M	X	M
M 19	X	X	X	X	X	X
M 20	X	X	X	X	X	M
M 21	M	X	M	X	X	X
M 22	X	X	X	X	X	X
M 23	X	X	X	X	X	X
M 24	X	M	M	X	X	M/D
M 25	X	X	X	X	X	X
M 26	X	X	X	X	X	X
M 27	X	X	X	X	X	X
M 28	X	X	X	X	X	X
M 29	X	X	X	X	X	X
M 30	X	X	X	M/D	X	M/D
M 31	X	X	X	X	X	X
M 32	X	X	X	X	X	X
M 33	X	X	X	X	X	X
M 34	X	X	M/D	X	X	X
M 35	X	X	X	X	X	X
M 36	M/D	X	X	X	M/D	X

Legend:

X - Work package duration (start to final months)

D - Month when deliverable will be produced

M - Month when milestone will be reached

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Collaborating partners

#	Institution	Contact person (First name and Last name)	Address (City, Country)
1	The Medical University of Vienna, Department of Epidemiology, Centre of Public Health	Christian Vutuc	Vienna, Austria
2	Ministry of Health, Health Monitoring Unit	Pavlos Pavlou	Nicosia, Cyprus
3	Obstetrics Clinic, Rigshospitalet, Københavns University	Jens Langhoff Roos	Copenhagen, Denmark
4	Estonian Institute for Population Studies, Tallinn University	Luule Sakkeus	Tallinn, Estonia
5	Bavarian Working Group for Quality Assurance	Nicholas Lack	Munich, Germany
6	Athens University, Department of Ob/Gyn	Aris Antlakis	Athens, Greece
7	Vasary Kolos Teaching Hospital, Department of Obstetrics and Gynaecology	István Berbik	Esztergom, Hungary
8	Economic and Social Research Institute, National Perinatal Reporting Scheme	Jacqueline O'Reilly	Dublin, Ireland
9	Pediatric Hospital of Baby Jesus, Unit of Epidemiology	Marina Cuttini	Rome, Italy
10	The Centre of Health Economics	Irisa Zile	Riga, Latvia
11	Department of Health Information, National Obstetric Information Systems (NOIS) Register	Miram Gatt	G'Mangia, Malta
12	University of Bergen, Medical Birth Registry of Norway	Kari Klungsøyr	Bergen, Norway
13	University of Porto Medical School, Department of Hygiene and Epidemiology	Henrique Barros	Porto, Portugal
14	University Medical Centre, Perinatology Unit	Živa Novak-Antolic	Ljubljana, Slovenia
15	University of Alcalá, Department of Health Sciences and Social Medicine	Francisco Bolúmar	Alcala, Spain
16	National Health Information Center	Mária Chmelová	Bratislava, Slovakia
17	Ministère de la Santé / Direction de la Santé	Yolande Wagener	Luxembourg, Luxembourg
18	Perinatal Center of the Institute for the Care of Mother and Child	Petr Velebil	Prague, Czech Republic
19	Center Of Health Information, Institute of Hygiene	Jone Jaselioniene	Vilnius, Lithuania
20	Department of Women's and Children's Health Uppsala University	Gunilla Lindmark	Uppsala, Sweden

Associated partners

#	Institution	Legal Representative (First name and Last name)	Address (City, Country)
1	Terveyden ja hyvinvoinnin laitos	Pekka, Puska	Helsinki, Finland
2	Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek (Netherlands Organisation for Applied Scientific Research)	Michael, Holewijn	LEIDEN, Netherlands
3	Université libre de Bruxelles	Philippe, Vincke	Bruxelles, Belgium
4	Instytut Matki i Dziecka (National Research Institute of Mother and Child)	Slawomir, Janus	Warsaw, Poland
5	The City University'	Constantine, Arcoumanis	London, United Kingdom



ANNEX 1b

Acronym: EURO-PERISTAT Action

Title: Promoting better health for mothers and babies through routine European monitoring of perinatal health and health care

Problem analysis including evidence base

Healthy pregnancy and safe childbirth are goals of all European health care systems. Despite major improvements in past decades, mothers and their babies are still at risk during pregnancy, delivery, and the postpartum. Babies born too early are more likely to die and to have long-term disabling neurological and developmental disorders than those born at term[1]. Preterm and low birthweight rates are stable, if not increasing, and reflect the limited success of prevention in comparison with developments in care[2]. Women continue to die during childbirth and a significant proportion of these deaths are associated with substandard care[3]. These adverse health outcomes occur more often among socially disadvantaged women and babies[4] and contribute to life-long health inequalities. Early life exposures, such as fetal growth restriction, may substantially increase susceptibility to chronic diseases in adulthood[5]. In the first-ever comprehensive European Perinatal Health Report (published 12/2008)[6], the EURO-PERISTAT project found wide differences in perinatal health indicators between EU Member States. The highest neonatal mortality rates were three times higher than the lowest rates (from 2 to 6 per 1000 live births). Significant variation was documented in stillbirth, preterm and low birthweight rates and maternal mortality ratios. Clinical practice also varied greatly: caesarean section rates ranged from 13 to 38% of all deliveries and episiotomies from 10 to 82%. These results raised questions about whether Europe's mothers and babies were receiving optimal care and about the efficiency and cost-effectiveness of health services[7,8]. Despite the added value of these data for European action and their availability in member states, this report cannot be reproduced from routine European health information systems. These systems do not include essential indicators and many indicators are not comparable due to differences in collection and reporting procedures.

Target groups

Our ultimate target groups are the more than 5 million pregnant women and their newborns in Europe every year whose health will benefit from the development of a health information system to support informed decision-making about health practices and policies. These decisions are made by diverse stakeholders who need reliable information, including clinicians (obstetricians, neonatologists, midwives, and neonatal nurses), policy makers in health ministries, maternal and child protection offices, and insurance and quality assurance agencies as well as pregnant women and their families. The organisation of these stakeholders varies between the MS. Policy-making is highly centralised in some countries and is shared among regions in others.

EURO-PERISTAT has created a map of perinatal decision-making in Europe along with a database of key actors. We conducted a literature review and a series of semi-structured interviews to better understand the terrain of decision-making, and then a questionnaire among our network of experts to identify actual contacts within countries. The range of contacts differs between countries, but includes representatives from ministries of health, national professional associations of obstetricians, gynecologists and midwives and user organizations.

This framework needs to be continually updated – because the leaders of these groups change - but it provides a solid basis for organising outreach and dissemination. Methods for reaching these stakeholders include sending reports (by post, email, website links), personal contacts, scientific articles, presentations in scientific congresses and the project website. Media outreach - including national and international press



releases and press conferences - is necessary, in particular for reaching users. Interest in the first European Perinatal Health Report was high, with more than 110 articles in the press across Europe and 3900 downloads of the report from our website.

Methods and means

The Euro-peristat project has developed methods for obtaining consensus and producing high quality data. These include (1) **ensuring broad geographic representation** – the Europeristat project aims to identify experts from each country to facilitate exchanges with national institutions. Previous phases of the project identified experts in each country and we have one official representative per country on our scientific committee. In the current project, we will extend the geographic coverage further by adding members from Romania and Bulgaria and other candidate countries, if there is interest. When working groups are created, invitations to participate are extended to the larger group (2) **Using scientific methods for achieving group consensus.** We have used a consensus process, based on the Delphi technique, successfully to obtain agreement on our indicator list and on an action plan for sustainable health reporting. The Delphi is a formalised method whereby participants respond to a successive series of questionnaires with the aim of achieving a consensus on key principles or proposals. Participants rank items by priority or importance and may provide comments. The benefits of this approach are anonymity, iteration (allowing participants to change their opinions), feedback in which participants are provided with the distribution of the group's previous responses, and the derivation of summary measures of agreement. (3) **Quality analysis and dialogue with data providers.** We believe in engaging data providers in data analysis and interpretation because an on-the-ground understanding of data collection and management procedures is essential for achieving high data quality. Because of the large differences in clinical practice, it is also important to obtain clinical input when interpreting variations in health indicators.

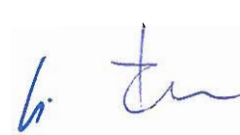
These key principles are integrated into the methods for each objective below:

Objective 1: 1. Establish a technical working group including members of the EURO-PERISTAT scientific committee and EUROSTAT to identify the relevant legal and technical criteria for indicators in liaison with the ECHIM Joint Action. This working group will review each indicator and propose changes when necessary. 2. Write a case study report for each MS detailing the strategies for integrating EURO-PERISTAT indicators into routine reporting in collaboration with ECHIM. 3. Include members of EUROSTAT in a data quality workshop after collection of 2010 data, to promote a harmonised approach to data cleaning and validation.

Objective 2: 1. A report on options for legal frameworks and financing sources for a network will be written based on advice from legal experts. 2. A collaborative consensus method with the scientific committee and other key partners will establish the governance structure (membership, executive bodies and decision-making procedures).

Objective 3: 1. Compile proposals from key informants on modifications to the EURO-PERISTAT indicator list. Conduct a structured consultation process with scientific committee members and data providers to decide on updates. 2. Analyse data from selected MS on: generating maternal morbidity indicators from hospital discharge data and quality criteria (registration criteria, missing data and data linkage). 3. Develop a protocol for broader analysis of social inequalities, including health care as well as outcome. 4. Hold two data quality workshops at the Scientific Committee meetings to present analyses and endorse common guidelines.

Objective 4: 1. Collect population-based data on EURO-PERISTAT indicators from routine sources in all European MS and other participants for the year 2010 based on an updated data collection protocol, including a comprehensive quality review. 2. Generate output tables on perinatal health indicators for the project website 3. Produce a European Perinatal Health Report assessing geographic, temporal and socioeconomic variations in the care and health of pregnant women and newborns. 4. Analyse perinatal health data on key themes with clinical and policy relevance including the rise of preterm birth and perinatal mortality rates and social inequalities, for broad dissemination.



Objective 5: Identify members for the network from BG and RO and from other candidate countries (through outreach to statistical and scientific institutions) and perform on-site visits.

Expected Outcomes

The principal project outcome will be a high quality, innovative, internationally recognised and sustainable European perinatal health information system. This system will produce data and analysis on a regular basis for use by national, European and international stakeholders who make decisions about health and health care of pregnant women and newborns. This health information system will reinforce European excellence and innovation by strengthening collaboration between data providers, epidemiologists and user associations in a formalised Surveillance Network. We expect that the discussion about the variation in indicators of health and care between countries and over time between groups of stakeholders from different countries and disciplines will generate new research questions about prevention of diseases and medical conditions and quality of perinatal and newborn care. Outreach to research institutes and an interface with calls from DG-Research will be encouraged. These data will provide information for the European commission and individual MS to define priorities for action with respect to the health and care of pregnant women and infants. Accordingly, improved policies and practices are expected outcomes. For instance, reports from individual countries show that preterm birth rates are rising[9,10], but data on trends in Europe are not available. Preterm birth is associated with higher mortality and long-term neurodevelopmental impairment; if the incidence is rising in Europe, a concerted effort among MS and within Europe could identify the causes and inform prevention strategies. If preterm birth is rising in some, but not all countries, it may be possible to learn from the existing policies in countries where rates remain stable. Other examples of outcome data which are important for policy makers, but currently unavailable, are mortality rates for high risk infants (very low birthweight or very preterm infants) and rates of maternal morbidity related to childbirth. Information on the use of key interventions will contribute to a discussion of best practices. Finally, by making data and analysis easily accessible through downloadable reports and tables from the internet and through media dissemination efforts, the project will empower users of health care services.

Innovative nature, technical complementarity and avoidance of duplication with other existing actions at EU level: This project fills a current gap in European health reporting. Only limited data are available at the EU level on the health and health care of pregnant women and newborns in the perinatal period. By coordinating with EUROSTAT and ECHIM we aim to eliminate any duplication in health reporting systems, reinforce complementary initiatives and improve the quality of health indicators available to decision-makers. The project fosters valuable links with other EU project's related to maternal and child health, including EUROCART and EURONEONET.

External and internal risk analysis and contingency planning

Principal risks, contingency plans and measures to mitigate risk:

1. It may be difficult to integrate a large number of indicators into EUROSTAT given their strict inclusion criteria and complex negotiation procedures. We have considered this risk in setting realistic goals (10 indicators or more). The scientific committee members will lobby their health ministries and statistical authorities to gain support for this process; many people contributing data to EURO-PERISTAT already provide data to EUROSTAT. For indicators that are not suitable, the collaboration with ECHIM offers more flexibility. Responsibility for monitoring non-integrated indicators will be delegated to the Surveillance Network. A mechanism for adding indicators as they become broadly available will also be negotiated.
2. Finding an appropriate legal structure for the Surveillance Network may be complicated by inconsistencies between the national legal status of public institutions and the creation of a European (probably private) legal

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entity and by disagreement on the location of the legal entity headquarters/applicable law/governance. To mitigate this risk we will enlist the participation of legal officers from the institutions that are interested in playing a role (through the creation of a Legal Officers Network) and will seek independent external legal counsel. The scientific committee will vote (two-thirds vote with one vote per participating country) to make a final decision if a consensus does not emerge.

3. Unequal capacity in data systems between European MS is a challenge for this project because national investments are necessary to improve data availability and quality. We have had past success obtaining universal adherence, but contributions differ in breadth. Contingency plans include providing technical support to countries with less developed infrastructure (including site visits). Methods for analysing and reporting data incorporate the heterogeneity of data systems within Europe.

4. Our project relies on a commitment within the EU to support European health information systems. At present, the funding mechanisms for permanent networks or initiatives are not clearly developed. It is unclear if the MS would show sufficient interest to fund on-going surveillance work in the absence of EU funding for networks or additional funding for existing systems (Eurostat/ECHIM).

Horizontal Work package - Description of the work

Work package number 1

The organisational structure of Europeristat action is as follows:

- *The Coordinator J. Zeitlin (INSERM)* monitors compliance by the beneficiaries with their obligations under the Grant Agreement
- *The Scientific Committee (SC)* is responsible for the major strategic, scientific, political and financial decisions to be taken for Europeristat action
- *The Executive Board (EB)* provides assistance to the coordinator for the scientific management of Europeristat action

The Coordinator of the action will act as the direct link and intermediary between the Commission/Agency and the beneficiaries, receive and distribute payments, keep accounts of all aspects of the project including financial efforts and reports, and ensure that the project follows the pre-signed contractual obligations.

The Scientific Committee (SC) is the principal decision-making body of Europeristat action and must endorse the work programme and major decisions.

It is composed of:

- one representative of all Associated and Collaborating partners
- one representative per EU Member State not participating in the present action
- one representative from Norway
- it is planned to include during the course of the project representatives from candidate countries (see specific objective 5).

The SC provides scientific oversight and endorses project decisions and outcomes. Activities of the SC members include:

- Participation in the project working groups (based on their interests and availability)
- Coordination of data collection activities in their countries
- Elaboration of a national dissemination plan with assistance from the coordination team
- Nomination of other experts to assist with project activities, such as data collection and dissemination
- Principal liaison for communication about the project in their respective country



The Executive Board (EB) will assist the Coordinator in the management and coordination of the project and helps the coordinator to draft work plans and review the day-to-day execution of the project. It is composed of one representative of all associated beneficiaries (AB) and 3 collaborating partners (N° 7 Hungary, N° 13 Portugal, N° 14 Slovenia)

A project manager will be hired (50% time) to assist the coordinator with coordination & dissemination activities (WP2).

The work to be carried out as part of this work package includes:


- Coordination and governance • Draft an agreement with the AB and other members of the SC establishing the roles of all partners and decision-making rules, including participation in work package task teams. This agreement will be endorsed by the SC • Monitor compliance by AB with financial and grant agreement rules and negotiate and implement contract amendments, if necessary.
- Communication • Develop a password-protected web-based communication platform with all project essential documents (contracts, reports etc...) • Regularly update this platform with project documents and notify partners using an up-to-date email list.
- Project meetings • Establish the objectives, agenda, and minutes for Executive Board and SC meetings. • Carry out the logistic and organisational work, solicit and distribute documents for the meetings
- Routine technical reporting • Provide guidelines for technical and financial reporting (cost statements, time sheets) at the beginning of the project. • Compile financial, administrative and scientific reports for routine technical reporting and prepare technical reports for internal review. • Assist partners on administrative and financial issues during the reporting phase.

Work package number 2

Previous work by the EURO-PERISTAT project identified the stakeholders involved in decisions related to perinatal health in member states (through informant interviews, partner surveys and an evaluation survey). This framework will be expanded to include new members and new target audiences and, in particular, user associations.

The dissemination strategy (to be formalised in a written report within the first 12 months of the project) will include the following tasks:

1. Stakeholder identification and outreach • Revise and develop the EURO-PERISTAT stakeholders' contact list (at present this list includes over 500 names and email addresses) to incorporate changes to governance within member states, to include new member states and to expand to professional and scientific groups, regional-level stakeholders and user associations. • Keep up continued contact with these stakeholders through updates on project activities (by emails linking to the project website – using a mailing list feature, stakeholders who have signed on will be notified of changes to the website; stakeholders who have not signed on will be sent a brief update, and website link, every 6 months). • Develop a list of government level contacts within each MS.
2. Development of dissemination tools and methods • Expand and maintain the project website and develop areas for distinct stakeholder groups, including clinicians, policy-makers and user groups. • Prepare documents about the project (including a promotional leaflet) for the website. • Support SC lobbying of government decision-makers about project initiatives. • Develop an integrated media strategy on the national and international levels to disseminate new data on perinatal health. • Track media attention to analyse our impact and improve the media strategy (see WP3). • Present project findings in national and international



scientific congresses and publish scientific papers in professional journals and international peer-reviewed journals. • Respond to requests from DG-SANCO for contributions to European-led dissemination efforts.

Work package number 3

The project's evaluation strategy includes 3 components:

1. Internal peer review of scientific progress and quality • At each scientific committee meeting, working groups will present their work and solicit comments and suggestions for improvement • The first scientific committee meeting will take place during the first year of the project. At the second scientific committee meeting, 2010 data on indicators will be presented and outliers and unexpected findings will be discussed in the context of a data quality review. • For each interim technical report, the project planning chart and indicator list will be assessed. Where the project falls short of its initial objectives, an explanation and proposal for redressing the problem will be included in the report.

2. External Advisory input and progress reviews. During the first 6 months of the project, an external scientific board will be established with 6 members from European or national perinatal health institutions (researchers, clinicians) as well as institutions with an expertise in routine national data collection and reporting. The members of this board should not be associated with the institutions that have participated in the EURO-PERISTAT project. The executive boards of the following associations will be approached and asked for nominations: The European Association of Perinatal Medicine, European Society of Paediatric Research, International Confederation of Midwives, European Board and College of Gynaecologists and Obstetricians (EBCOG) and the European Public Health Association. Our aim is to identify four members with expertise in obstetrics, a neonatology, midwifery and public health or health services research. Additionally we aim to invite two experts working outside of the EU who are involved in successful routine data collection and reporting systems on perinatal health (in particular, experts from Australian, Canadian and US systems).

Members of the board will be asked to provide their comments on the process and output of the indicator review in the 1st year and the plans for developing a surveillance network. An evaluation will also be carried out in the 2nd year of the project. Members of the board will be invited to attend the SC meetings and to review project documents before these meetings. The board will identify areas in which the project is achieving its aims and areas in which more work is necessary. The SC will use these recommendations to propose changes to the work plan or project organisation.

3. Evaluation of the European Perinatal Health Report (EPHR) • A web-based evaluation will be undertaken among the EURO-PERISTAT contacts to assess reactions to the EPHR using the methodology used to evaluate the 1st EPHR (and allow comparisons with the first report) • The number and breadth of media coverage on the 2nd EPHR will be assessed and compared to that obtained for the 1st EPHR with the aim of achieving expanded coverage in all countries participating in the report.

Core Work Package - Description of the work

Work package number 4

Work package 4 includes activities to achieve sustainable perinatal health reporting on the European level and involves two strategies. The first is to integrate Euro-peristat into routine systems and in particular



Eurostat and ECHIM. This would ensure sustainability because the indicators would be compiled regularly through routine MS data reporting and reported in EU websites. The work to propose indicators that can be integrated must be done in collaboration with these two groups. The second complementary strategy is to develop a formal network which can seek sustainable sources of funding from the EU as well as member states.

Integrating EURO-PERISTAT indicators into European statistical systems

1. Establish a technical working group including members of the EURO-PERISTAT SC, EUROSTAT and members of the ECHIM Joint Action 2. Assess which EURO-PERISTAT indicators fulfil EUROSTAT legal and technical criteria for inclusion in routine data collection 3. Describe strategies in each MS for integration of EURO-PERISTAT indicators into routine EUROSTAT reporting 4. Detail the resources needed on the EU level to integrate EURO-PERISTAT indicators into routine data collection and reporting 5. Develop a written proposal, with a specified time frame and submit it to member states for endorsement. These tasks will be coordinated by Mika Gissler and other members of the Scientific Committee with an interest and expertise in routine data collection with EUROSTAT. The project coordinator will also participate in this group.

Creating a European Perinatal Health Surveillance Network

This network aims to maintain scientific involvement in perinatal health surveillance, develop indicators for future inclusion in European statistical systems, collect data from national sources when European sources do not yet exist and analyse data from European and national sources for broad dissemination to target audiences. The work includes: 1. Create a working group of SC members to execute this work, led by the WP leader 2. Identify legal contacts in their institutions to participate in a Legal Officials Network to provide advice. 3. Carry out a Delphi consensus process with SC members and other invited experts to specify governance structure 4. Obtain external independent legal advice on frameworks for constituting a European Network (subcontractor) 5. Explore institutional collaborations with European perinatal scientific societies 6. Produce a report detailing possible options for discussion at the 2nd Scientific Committee meeting 7. Develop a written proposal, with a specific time frame and submit to member states for endorsement

This process will be coordinated by INSERM, including implementing the Delphi consensus process. All members of the SC will be asked if they wish to participate in the working group. These SC members will identify the appropriate legal officials from their institutions and invite them to participate.

Work package number 5

Develop capacity for high quality health reporting 1. Update the EURO-PERISTAT indicator list to reflect modifications in health priorities through a structured consultation process with the SC. Proposals for modifications, solicited from experts, will form the basis for this process which will apply the same criteria as used in previous DELPHI processes. 2. Explore the adoption of quality assurance methods utilised by EUROSTAT, OECD, WHO, EU Joint Actions (ECHIM, EUROCAT...) 3. Develop protocols for analysis of data from selected MS on: (1) generating maternal morbidity indicators using hospital discharge data and on (2) quality criteria (registration criteria, missing data and data linkage). 4. Develop a protocol for broader analysis of social inequalities, including health care as well as outcome and using both maternal education and migrant status as indicators (protocol will be tested in selected countries before integration). 5. Hold two data quality workshops at the SC meetings to present analyses and endorse common guidelines: (1) Workshop on the quality measures to be integrated into the data collection exercise on 2010 data -see WP6; (2) Workshop on analysis methods which can be applied to these data post-collection.

This WP will be coordinated by INSERM with input from the team at City University and TNO. Marie-Hélène Bouvier-Colle (INSERM) who coordinated work on maternal morbidity in the previous phase will be

in charge of task 3. Alison Macfarlane (City U) and Sophie Alexander (ULB) will manage task 4. Mika Gissler will oversee task 1. All members of the SC will be invited to join working groups on these themes.

Expand EURO-PERISTAT's geographic scope. The aim is to integrate new members from Bulgaria, Romania and other interested candidate countries into all project activities. We will follow the following process to integrate new countries and identify scientific committee representatives (one from each country): 1. Contact statistical and scientific institutions in these countries to identify interested experts. 2. Organise site visits to present the project, assess capacity and provide technical support 3. Support participation in project working groups and data collection activities. The work of identifying scientific committee members will be coordinated by INSERM with assistance from the SC. Scientific committee members will be asked to: participate in the project working groups (based on their interests and availability), coordinate data collection activities in their countries, nominate other experts to assist with project activities, such as data collection and dissemination. The SC member is the principal liaison for communication about the project in their respective country

Work package number 6

1. Modify the EURO-PERISTAT Excel based data collection protocol developed by TNO for 2004 to incorporate the operational guidelines specified in the EURO-PERISTAT action plan, take into consideration new guidelines for better quality developed in the first year of the project (WP5) and to allow internet transmission of aggregated data. 2. Consult with EUROSTAT and ECHIM to ensure compatibility with their procedures for data collection and presentation (see WP4) including verifying that EURO-PERISTAT software is compatible with the that used by EuroStat and ECHIM.. 3. Use the updated protocol to collect data in participating countries. The data collection instrument will be sent to each scientific committee member who will be responsible for compiling the data themselves or for delegating the task of completing the instrument to another expert or institution. 4. Verify data quality in collaboration with data providers from each participating country and send out queries to the scientific committee members and request for updated or corrected data whenever required. 5. Modify the EURO-PERISTAT templates for the output tables from the European Perinatal Health Report to incorporate the deliverables specified in the EURO-PERISTAT action plan, and produce tables for each indicator using the modified templates for the EURO-PERISTAT output tables. Obtain endorsement of data tables from each participating country. 6. Create a finalised EURO-PERISTAT 2010 data base which can be used to produce customised data tables on the project website. Merge this database with EURO-PERISTAT data collected from 2000 and 2004. 7. Set up analysis groups on specific themes to write narrative reports to accompany data on the website and to develop analyses for scientific presentations and publications. The analysis groups will be set up and begin their work at the 2nd Scientific Committee Meeting. 8. Coordinate the production of the second European Perinatal Health Report on 2010 data in 2013.

Ashna Mohangoo (TNO). Professor Simone Buitendijk (TNO) will be the scientific leader. As part of her academic functions, she will actively contribute to the EURO-PERISTAT Action project with disseminating and lecture activities, capacity and alliance building on the topic of Maternal Health and Midwifery Science at the Academic Medical Center of the University of Amsterdam, and on the topic of Preventive Child Health Care at the Leiden University Medical Center. All members of the SC will actively contribute to this WP by providing data. Jennifer Zeitlin (INSERM) and Ashna Mohangoo (TNO) will coordinate the production of the second EPHR and will coordinate writing groups on specific themes.

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