Project funded in 2005 - Strand 1: Health Information

EURONEOSTAT - European Information System to Monitor Short and Long-Term Morbidity to Improve Quality of Care and Patient-Safety for Very-Low-Birth-Weight Infants

Description

Action
Health information

Area of activity
Developing and co-ordinating the health information and knowledge system

Summary

BACKGROUND.
Prematurity, that is birth before the 37 completed week of gestation, is a significant health problem in Europe, and its prevalence is increasing, as is the rate of Very-Low-Birth-Weight (VLBW) infants. Those very immature, of less than 32 completed weeks of gestation and of a birth weight of less than 1,500 g, have an increased risk for short- and long-term morbidity and mortality, and its care consumes a large and growing amount of health interventions and results will be adjusted by weight and gestation. Percentiles and extreme values will be checked.

OBJECTIVES.
We aim to develop an Information System to assess quality of health care delivered to very prematurely infants (birth weight less than 1,500 g and/or less than 32 wks) at different units, regions and EU countries. This could contribute to improve the health status of those high-risk infants, and detect any outcome inequalities that might exist. To do this we will:

1. create and validate a set of neonatal indicators to evaluate the specific rates of neonatal and post-neonatal mobility;
2. test the hypothesis that gestational age is a better indication of short- and long-term risks than birth weight;
3. use specific health indicators given by participating units for benchmarking to identify areas with opportunities to improve quality-of-care, and monitor their success, in selected areas, we will perform inter-regional comparisons to identify outcomes affected by variability of clinical practices and health delivery systems;
4. develop and validate a minimal follow-up dataset to assess the quality of life at 24 months, and an expanded questionnaire to be tested at selected institutions or regions;
5. assess the predictive value of perinatal indicators for the health status at 24 months; and develop software and tools to collect, transfer, validate, standardise and compare the perinatal and follow-up data collected, using up-to-date ICT.

METHODOLOGY.
A prospective, multicentric descriptive study will be designed to determine birth weight and gestational age specific morbidity rates in the target population of live-born infants of birth weight <1,500 g and/or gestational age <32 wks born at partner’s units. Maternal, socio-economic, perinatal and neonatal events, interventions and outcome will be recorded (all procedures will adhere to protection data and personal identity legislation).
To evaluate health status at a 36 moths, a minimum data set will be developed, a more complete questionnaire to assess health status will be developed to be used by selected units. We plan to collect data from some 3000-4000 VLBWI from more than 50 NICUs at partner’s institutions and from some regional (Liverpool, Basque country and Navarre,..), and national networks (Spain, Portugal, Switzerland, Finland,..). Data collection will be performed in a prospective way in babies born in 2005, 2006, and 2007 at collaborating units.
No retrospective data will be used. Some information from each NICU will be gathered about its infrastructure, personal, procedures… Prospective data collection will start at birth, and stop at death or discharge. A 1st data quality check will be done at data entry, by automatically verification. An Internet-based interactive website will be developed, with three levels of access: unit, region and country. Quality checks will be done, and discrepancies/incoherences looked after, to notify units. 5% of datasets will be double-checked by random.
Once validated, data will be pooled and housed in the web as a reference population. Centres will autonomously perform statistics to know its relative positioning and to display and download of statistics/graphics, but will be informed of extreme values. Indirect standardised rates will be used to overcome effects of population weight composition, by taking study-wide rates and applying them to that of each unit. Perinatal and neonatal events, interventions and results will be adjusted by weight and gestation. Percentiles and extreme values will be check to identify variability of interventions and outcomes by small area method. Standard epidemiological procedures will be used to detect events associated with adverse outcomes.
INNOVATION.
Prematurity is a prevalent health problem, but in Europe there is no systematic recording of standardised specific morbidity data. Only in a few European regions and countries, such data is collected. In fact, over 50 European NICUs identified the need and sent data and money, to a private initiative in the USA, Vermont-Oxford Neonatal Network. Technological progress is needed in medical networking, since now data flows on paper or e-format, and a coordinating centre performs all quality-control comparisons, that sends back to units as a fix set of items, again in an I.S. ICT to permit among others: direct web-based data submission and extraction from preset databases, autonomous quality-control in real-timed. These would permit to assess quality improvement initiatives, comparisons with other units at a region, national or European level, Designed regional/national leaders could perform comparisons to other regions/ countries, decrease the operational costs. 

SYNERGIES.
There is neither duplication nor total or partial overlap between our initiative and any other activities carried out by the EC. Two Public Health initiatives, Eurostat and Peristat collect only neonatal mortality data, but not neonatal morbidity or long-term outcomes. We will contact leaders of both Peristat and Eurocat initiative to ensure a good collaboration, to avoid overlaps, and to use definitions and indicators already developed by them. Recently, an International Collaboration of Neonatal Networks was created to develop a common dataset of health indicators, aiming to help WHO to include the assessment of health status of VLBWI.

More info...
2. define and agree rights and obligations related with dissemination of results for each partner organisation depending on the nature of such organisation;
3. develop, present and discuss the information about results of the project for the general public audience;
4. Develop a final dissemination strategy to access to alternative funding sources to assure continuance once the project finishes

Work package 3: Evaluation of the project
The general objective of this WP is to maintain a continuously active process allowing to identify, analyse and report any deviation from the expected path of the project in order to react efficiently as soon as any problem is detected. For that purpose, the specific objectives of this WP are:

1. the development of an agreed evaluation strategy that involves all partners and the EC,
2. the definition of an evaluation procedure based in a pyramidal sequence of validations, and information flows, from the auto-evaluation of each partners activities, to the periodic evaluation of the overall project execution at the management meetings,
3. the continuous evaluation based on the previous strategy and procedures.

Work package 4: Neonatal morbidity indicators
To evaluate the use of gestational age rather than birth weight as a major specific risk indicator for morbidity of VLBWI. This is because weight its easily and precisely measured, but does not truly reflects the degree of maturity of the newborn, been influenced by intrauterine growth (30% of VLWI are under-grown at birth). Gestational age, is now routinely used, and precisely measured by early foetal sonography. Moreover, we will also evaluate the combined use of birth weight and gestational age, since maybe babies of a gestation less than 32 wks, even if weight over 1,500 g, might have a greater risk than those below this weight, if are more mature. These strategy could allow to independently evaluate the two main cellular and biological foetal process, growth and maturation.

Work package 5: Standardised comparisons of morbidity outcomes
To allow partner’s units to perform standardised mortality and morbidity outcome comparisons to other units of similar in size or level of care, and to those of all units polled together. These will allow them to identify differences in clinical practices, morbidity outcomes, identify areas with opportunities to improve quality of care and to latter monitor the success of their quality improvement initiatives. To develop a summary report with results from all participating units, that could be used by any other NICU from Europe or else were to know its relative position for any of the items included in the perinatal dataset.

Work package 6: Minimal dataset of follow-up indicators
To develop and validate a minimal follow-up dataset of indicators to assess quality of life of VLBWI at 24 months of corrected age. The recording of the perinatal and follow-up datasets will permit to study the capacity of the perinatal indicators to predict the health status at 2 years. Moreover, a more detailed toll to assess the health status at follow-up at 24 months of corrected age will also be developed and evaluated.

Work package 7: Outcome research
- To use the perinatal indicators to monitor and quantify clinical variability among centres, and if found, nested studies will be proposed to identify the factors that could be responsible for the observed differences.
- To test the hypothesis that gestational age is a better indication for short- and long-term mortality risk than birth weight for VLBWI.
- To use of the perinatal indicators to attempt to predict the health status at 2 years. It is true that genetic, socio-economical, educational, cultural and other postnatal factors determine the health status in early infancy as it those latter on in life. However, it is also true that prenatal, perinatal and neonatal events also influence this status; ands so it could be use to predict health status at 2 years of corrected age.

Work package 8: EuroNeoSafe: a Patient Safety Initiative
To promote a patient-safety culture at participating NICUs, by establishing a voluntary, blame-free reporting system for adverse events (incidents and near-incidents). An internet-based system to house the safety information will also be created. This system will enable accelerated learning from the adverse events reported for all medical and nursing staff at participating units. We aim to promote patient safety by establishing an internet-based exchange of safety information derived from a system of voluntary, blame-free reporting of adverse events at the units level, under the name of EuroNeoSafe. Dr. H. Molednijk has developed such an initiative (Neosafe) in 9 out of 12 eligible Dutch units will participate in a nationwide project.

Work package 9: Software and Website
To develop the necessary software and informatics tools to record, transfer, validate, standardise and compare the perinatal and follow-up data collected, by use of up-to-date, ICT to facilitate incoming flow of data and the outflow of standardised comparative results.

Interim Report, February 2007  (790 KB)

Annexes:
- Annex 1: Kick-Off Meeting Minutes
- Annex 2: 6th Month Management Meeting Minutes
- Annex 3: 10th Month Management Meeting Minutes

Description - Financing - Outcomes - More Info
Statement of project aim(s) and objectives

General objectives: The ultimate strategic goal of the project is to develop an Information System to assess and improve quality of the health care given to very premature infants (gestation less than 32 wks) or of Very-Low-Birth-Weight (VLBWI; birth weight less than 1,500 g). Specifically, we aim to reduce their neonatal morbidity and mortality and improve patient safety, health status at 2 years, and to detect variability of clinical practice and outcome inequalities that might exist among units. To achieve those aims, we propose to design, collect, validate and implement a standardised set of birth weight and gestational age specific indicators. We plan to establish and maintain a data-base with a set of prenatal events, neonatal interventions and neonatal and long-term outcomes to assess the quality of care of the given in participating Neonatal Intensive Care Units (NICU). Data collected could also be used by health authorities to take decisions related to health programs and policies to improve the care of VLBWI. The project hopes to contribute to improve the quality and safety of the health care provided to VLBWI and their families by:

1. Data collected could be of use by NICUs to compare their results to those of other institutions, by applying the same criteria (“benchmarking”), to identify areas with opportunities to improve care, and to monitor the success of the quality-improvement and patient safety effort to achieve those aims (“internal audit”).
2. The indicators developed could be used by health organisations to evaluate the health programs, resources, and priority settings dedicated to short- and large-term care of VLBWI.
3. Knowledge of clinical variability of the care process and outcomes could provide insights into better ways to deliver care and to promote wide-scale consensus in policies and strategies to be use for care of VLBWI.
4. To prove the hypothesis that gestational age rather than birth weight should be used as a risk indication. Weight has been traditionally used since is easily measure, but does not truly reflect the degree of maturity. Gestational age is now routinely and precisely measured by early foetal sonography.

This project could ultimately contribute to consolidate “EuroNeoNet”, a platform affiliated to the European Society for Neonatology (ESN/ESPR) to a) enhance neonatal networking to help professionals to promote a culture for quality of care improvements and patient safe, family-cantered and developmental care, dissemination of evidence-based interventions by e-learning, evaluate clinical variability, dissemination results in professional meetings and effectively conducting academically-driven clinical trials, case-control, cohort, cluster and nested studies. For all above summarised reasons, the development of a specific neonatal and a minimum follow-up indicators to meet the specific information needs of VLBWI in Europe seems mandatory, and is possible by using data gathering by a European Network of Neonatal Units.

Specific objectives

The strategic aim of the project is to develop an information system to assess the quality of health care delivered to very premature infants (birth weight less than 1500 g and/or gestational age less than 32 wks) in European institutions, countries and regions. We plan to reduce neonatal morbidity and mortality and improve their health status at 2 years, and to detect any inequalities that might exist. To achieve aims below, we plan to collect data from some 3000-4000 VLBWI a year form more than 50 institutions, from associate and collaborating partners, as well as from some regional (Liverpool, Basque country and Navarre,...), and national networks (Spain, Portugal, Switzerland, Finland,...). The principal objective is to create and validate a set of neonatal indicators to assess clinical variability among centres if found, nested studies will be proposed to identify factors that could be responsible for the observed differences.

1. To develop standardised morbidity indicators, to assess the health care process and outcome results between participating units over time (benchmarking). In selected regions in wich a quasi-population-based data will be gathered, inter-regional comparisons will be performed to identify differences in outcome related to clinical variability. The indicators will also help units to identify areas with opportunities to improve quality-of-care (external audit), and to monitor the success in their improvement efforts. If significant clinical variability among centres if found, nested studies will be proposed to identify factors that could be responsible for the observed differences.
2. To develop and validate a minimal follow-up dataset, to assess the health status of survivors at 24 months of corrected age. An expanded questionnaire, to more precisely assess the health status will also be developed, and tested at selected units or areas with existing follow-up programs (Madrid, Liverpool and Berne hospitals).
3. To assess clinical variability among units of the different strategies and interventions used, to know what are doing in the care delivery process of the VLBWI assisted.
4. To test the hypothesis that gestational age is a better indication for short- and long-term mortality and morbidity risk than birth weight. Weight-specific indicators are use by existing networks, since its recording is judged more accurate. However, now very early foetal sonography precisely determines gestational age within a week.
5. To develop and validate a minimal follow-up dataset, to assess the health status of surviving infants at 24 months of corrected age. An expanded questionnaire, to more precisely assess the health status will also be developed, and tested at selected units or areas with existing follow-up programs (Madrid, Liverpool and Berne hospitals).
6. To develop and validate the necessary software and informatics tools to record, transfer, validate, standardise and compare the perinatal and follow-up data collected, by use of up-to-date, Internet-based technologies to facilitate incoming flow of data and the outflow of standardised comparative results.

Methods

To achieve our aims a prospective, cohort, multicentric descriptive study will be designed to determine birth weight and gestational age specific morbidity rates in the target population of immature infants care at participating units. The key points are:

1. Target population. All live-born infants with a birth weight less than 1,500 g, and/or a gestational age of less than 32 completed weeks (31 wks+6 d) born and cared at participating units. Data from 3,000-4,000 VLBWI/year will be collected form more than 50 NICU at partner’s institutions and from some regional (Liverpool, Basque country and Navarre,...) and national networks (Spain, Portugal, Switzerland, Finland,...).
2. Perinatal dataset. Maternal, socio-economic, prenatal neonatal events and interventions, positive indicators and outcome variables will be recorded (parental consent sought). Items will be selected from those used by Vermont-Oxford Network for over 10 years. Latter, dataset will be adjusted to specific needs detected. Information from NICUs, related to infrastructure, personal, procedures, and level will be gathered.

3. Minimum follow-up dataset to evaluate health status at a 36 months will be developed, and follow that published years ago by A. Johnson at Oxford (Arch Dis Child Fetal Neonat 1997;76:61; 98;79:F4). A more complete questionnaire to assess health status will be developed. A more completed health assessment tool will also be developed.

4. Data collection and recording. Prospective data collection will start at birth at all partner’s units under their supervision, and will stop at death or discharge form unit.

5. Data and patient identity protection. Data that could direct or indirectly identify patients will remain within units. All procedures will adheres to international protection data and personal identity procedures and legislation. Partners are guarantors of safety of database, that will only be used to achieved the project’s aims.

6. Data validation and quality control. A data quality check will be done at data entry into the software at units, by automatically verification: outliers, completeness.

7. Data standardisation and analysis. Indirect standard rates will be used to overcome effects of population weight composition on comparisons of crude rates. Perinatal and neonatal events, interventions and results will be adjusted by weight and gestational age, and rates, percentiles and extreme values will be checked to identify clinical variability of interventions and outcomes. Centres will be informed of any situation of extreme values.

8. Interactive website and software. An Internet-based virtual environment will be set to allow:
   - public/private access to data levels: general, unit, region, country;
   - protection of patient data;
   - introduction and detection of discrepancies/incoherences/missing data;
   - centres could autonomously perform queries to know its relative position among other units displaying statistics/reports/graphics defined by user.