Children’s Health

EU DG SANCO Workshop

EuroNeoNet. A European Neonatal Network

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SPAIN

Luxembourg, Nov. 20-21, 2007
“European Information System to Monitor Short- and Long-Term Morbidity Outcomes to Improve Quality of Care and Patient-Safety for VLBWI” (Contract 2005/116)

“EuroNeoStat”

Funded in 2006 call for Public Health actions
EU Commission, Public Health Section
¿Is an Epidemiological Q-A System for VLBWI needed?

- Prematurity rates are increasing all over the World.
- Outcomes of VLBWI contribute significantly to Neonatal and Infant mortality (up to 80 - 90%).
- A small number of cases (1-2% of total births).
- All cases are immediately identified in hospitals.
- Large and increasing amount of health resources are consumed (Short- & long-term).
- Initial risk similar, so outcome directly related to quality of care.
- There are several Evidence-based interventions to improve outcomes (Antenatal steroids, surfactant).
- Nosocomial infection is still one of the principal problems (Preventable).
Mission (Strategic aim)

To develop I.S. to assess Q-of-C received by VLGA/VLBW infants (BW <1,501 g or <32 wks) in Europe, to contribute to the improvement of their health status, and detect any existing outcome inequalities.

We aim to minimise risks for all babies, so their outcome could be the same no matter where they are born.
EuroNeoStat. Objectives

1. To gather data from different NICU, regions & countries
   . Perinatal risk factors
   . Neonatal interventions
   . Short- and long-term outcomes

2. To study outcome variability and inequalities
3. To provide units with external audit (“benchmarking”)
4. To enhance Q-of-C improvement initiatives
5. To promote a culture for patient safety
Consortium: Associate partners

PI: Adolf Valls-i-Soler, JI Pijoán, Bilbao

1. CR Pallás, J de la Cruz, Madrid, Spain
2. M Hallman: Oulu, Finland
3. H Hummler, Ulm, Germany
4. O Claris:, Lyon, France, President ESN
5. C Corchia and M Cuttini, Roma, Italy
6. G Sedin, Uppsala, Sweden
7. T Stiris, Oslo, Norway, President ESPR
8. V Carnielli, Ancona, Italy, Educational and Accreditation ESPR/ESN
9. M Weindling, Liverpool, UK
10. H Molendijk, Zwolle, The Netherlands
11. H Halliday: Belfast, UK
Affiliated partners

- EU:
  1. Austria: Berndt Urlesberger, Graz
  2. Belgium: Bart Van Overmeire, Antwerp (+Network)
  3. Czech Republic: Richard Plavka, Prague
  4. Greece: Marietta Xanthou, Athens
  5. Hungary: Dr. Miklós Szabó, Budapest
  6. Ireland: Tony Ryan, Cork
  7. Poland: Janusz Gadzinowski, Poznan
  8. Portugal: Daniel Virella, Lisbon (Network 35 NICUs)
  9. Switzerland: Hans U Butcher, Zurich (Network?)
  10. UK: Mike Hall, Southampton

- Non EU:
  11. Turkey: Rahmi Örs, Erzurum
  12. Slovakia: Darina Chovancová, Bratislava
  13. Romania: Vasile Florin Stamatian, Cluj Napoca
  14. Russia: Lyubimenko Viacheslau, S. Petersburg
National Networks:

1) Integrated
   - Belgium
   - Portugal
   - Spain

2) Future:
   - Estonia
   - France
   - Italy
   - Norway
   - Sweden
   - Switzerland

www.EuroNeoStat.org
2006 Infant Cohort

- > 3,000 VLBW/VLGA infants
- From > 60 NICUs
- From 13 EU countries
- Birth Weight (mean ± SD) 1.068 ± 223 g
- Gestational age (mean ± SD) 29 ± 1 wks
- Set of 80 items (risk factors, intervention & outcomes)
- To be followed-up in 2008 (2 years CA for prematurely)
Data extraction:

1. Standard e-report
2. Internet-based self-obtained reports (from Website)
   - standardised
   - self-designed

- Comparisons to: - All / national / regional units

- According to password profile
  - individual units
  - regional level (regional networks)
  - national level (national networks)
2006 Data Analysis

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>BW (grams)</th>
<th>GA (weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>1,130</td>
<td>1,132</td>
</tr>
<tr>
<td>x ± SD</td>
<td>1,147.2 ± 355</td>
<td>28.7 ± 2.8</td>
</tr>
<tr>
<td>95% Mean CI</td>
<td>[1,126.5;1,167.9]</td>
<td>[28.5;28.8]</td>
</tr>
<tr>
<td>Median</td>
<td>1,160</td>
<td>29</td>
</tr>
<tr>
<td>[P25;P75]</td>
<td>[880;1,400]</td>
<td>[27;31]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>N</th>
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<tbody>
<tr>
<td>Corticoids (Com.)</td>
<td>599</td>
<td>54.5</td>
</tr>
<tr>
<td>Corticoids (Inc.)</td>
<td>259</td>
<td>23.5</td>
</tr>
<tr>
<td>Corticoids (None)</td>
<td>242</td>
<td>22</td>
</tr>
<tr>
<td>Caesarean Section</td>
<td>302</td>
<td>26.8</td>
</tr>
<tr>
<td>Vaginal</td>
<td>824</td>
<td>73.2</td>
</tr>
</tbody>
</table>

Mean = 1,147.16
Std. Dev. = 354.9
N = 1,130

Mean = 28.66
Std. Dev. = 2.8
N = 1,132
Mechanical Ventilation by Gestational Age

<table>
<thead>
<tr>
<th>Gestational Age (weeks)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤24</td>
<td>90.5%</td>
</tr>
<tr>
<td>25-26</td>
<td>97%</td>
</tr>
<tr>
<td>27-28</td>
<td>83.6%</td>
</tr>
<tr>
<td>29-30</td>
<td>80%</td>
</tr>
<tr>
<td>31-32</td>
<td>60%</td>
</tr>
<tr>
<td>&gt;32</td>
<td>40%</td>
</tr>
</tbody>
</table>

- **Yes**
- **No**

Mechanical Ventilation
Standardised mortality rate

by Birth Weight

by Gestational Age

by both, Birth Weight & Gestational Age
2006 Data Analysis
2006 Data Analysis

New proposal for Benchmarking graphs
2006 Data Analysis

Summary Results for Unit Code X
Year 2006
Percentual Position for Principal Results.
Mortality p-18

- Late Sepsis p-27
- Pneumothorax p-18
- PIVH (Grades III or IV) p-36
- O₂ on week 36 p-73
- Prenatal Steroids p-73

Summary Results for Unit Code Y
Year 2006
Percentual Position for Principal Results.
Mortality p-100

- Late Sepsis p-73
- Pneumothorax p-100
- PIVH (Grades II or IV) p-81
- O₂ on week 36 p-27
- Prenatal Steroids p-9
Comparison NICUs from countries 1 and 2
### Mortality against Gender

<table>
<thead>
<tr>
<th></th>
<th>NO</th>
<th></th>
<th>YES</th>
<th></th>
<th>TOTAL</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Male</td>
<td>511</td>
<td>83.9</td>
<td>98</td>
<td>16.1</td>
<td>609</td>
<td>54</td>
</tr>
<tr>
<td>Female</td>
<td>445</td>
<td>85.9</td>
<td>73</td>
<td>14.1</td>
<td>518</td>
<td>46</td>
</tr>
<tr>
<td>TOTAL</td>
<td>956</td>
<td>84.8</td>
<td>171</td>
<td>15.2</td>
<td>1127</td>
<td>100</td>
</tr>
</tbody>
</table>
Errors in the NICU

NICU: complex ambient many professionals on a hurry, stressed

VLGAI: small, ill & vulnerable

Type of errors: numerous
  - medication
  - procedures
  - equipment, ........
**WG-3  Patient safety**

**EuroNeoSafe**

- **What have we done so far**
  1. **WebSite**. Executive summary and links
     - e-Forum on Patient Safety
  2. Software for *Voluntary Reporting System* of near-incidents
  3. Draft **patient safety dataset** (taken from NeoSafe)
Welcome > Home

The **EuroNeoSafe** initiative is part of the **EuroNeoStat** project financed by [DG SANCO](https://ec.europa.eu/health) of the EC (project No 2005/116).

**Mission**

The **EuroNeoSafe** initiative aims to promote safe healthcare practices in Neonatal Intensive Care Units (NICUs) throughout Europe.

**Aim**

The **EuroNeoSafe** plans to contribute to the dissemination and promotion of a culture for patient safety in European NICUs.

To fulfill its aims, **EuroNeoSafe** website offers to interested neonatologists the possibility to collect by use of a specific free software incidents and near-incidents to be analyzed locally. Moreover, incidents could be shared with other participants in the forum (listserv) provided in this website, to promote the learning potential of all participants. With all these, the forum could become a virtual space to ask and answer questions on safe practices in the NICU. Also, through the network provided by **EuroNeoNet**, partners can be found to work on specific safety projects.

**The theme of EuroNeoSafe is: NICU Care is Safe Care!**

**Patient safety** is a serious concern in Europe. Recent studies show that health care errors occur in around 10% of hospitalisations. European cooperation on patient safety is needed to improve patient care for people all over the EU. Putting in place systemic approaches to ensure patient safety will help to increase overall quality of healthcare.
NOTIFICATION
SYSTEM FOR PATIENT SAFETY
EuroNeoStat. Um sistema europeu de informação sobre os resultados dos cuidados a recém-nascidos de muito baixo peso

Adolf Valls i Soler¹ e Daniel Virella², em nome da Comissão Directiva da EuroNeoStat*

1 - Unidade de Neonatologia e Unidade de Epidemiologia Clínica. Hospital de Cruces, Baracaldo, Bilbao, Espanha
2 - Registo Nacional de Recém-nascidos de Muito Baixo Peso. Secção de Epidemiologia da Sociedade Portuguesa de Pediatria
Research Briefings

EuroNeoStat: A European Information System on the Outcomes of Care for Very-Low-Birth-Weight Infants

A. Valls-i-Teixidó, V. Camellí, O. Claro, J. de la Cruz-Bétolo, H.L. Halliday, M. Hallman, H. Hummler, M. Werdin, on behalf of the Scientific Steering Committee of EuroNeoStat

Address of Corresponding Author

Neonatology 2008;93:7-9 (DOI: 10.1159/000105519)

Abstract

Sorry, there is no abstract. Read the first few lines of the text instead!

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Neonatal Networking:
A European Perspective

Adolf Valls-A-Soler,* Henry L. Halliday,*
Heinri Hummler*

Neonatal Networks
Teamwork is an important aspect of all fields of human knowledge, including health-related activities. Networking is a form of cooperation that can enhance the efficiency and effectiveness of any project by collaboration toward common goals. New Internet-based information and communication technologies increase opportunities for collaboration among scientists and clinicians. In the medical field, networking has been used to improve the quality of medical care by disseminating information on evidence-based effective and non-effective or dangerous interventions (eg, through the Cochrane Collaboration) and promoting high-quality clinical research.

Neonatal networking can be defined as collaborative work involving several neonatal intensive care units (NICUs) sharing a common protocol to collect standardized patient data for external audits (benchmarking), clinical trials, and quality of care improvement projects. The first example of successful neonatal networking appeared in 1952, when the National Institutes of Health sponsored a clinical trial of the restriction of supplemental oxygen delivery to very low-birthweight (VLBW) infants. It was performed in 18 NICUs and resulted in a sharp decline in the incidence of retinopathy of prematurity leading to blindness. Since then, a large number of sufficiently sized, well-designed, randomized clinical trials have been conducted and published, exerting a strong impact on neonatal care throughout the world.

Other neonatal networks have been established as stable, ongoing organizations that have wide missions, not only to perform high-quality clinical research but to promote excellence in clinical practice by the use of standardized comparisons of outcomes, teaching and training of health personnel involved in neonatal care, and setting of high standards for the care of preterm infants. Such networks are supported by public funds (eg, the National Institute of Child Health and Human Development [NICHD] Neonatal Network (3) and the Australian and New Zealand Neonatal Network [ANZNN] (4)), membership fees (eg, the Vermont-Oxford Network [VON] (5)), private grants (eg, the Canadian Neonatal Network [CNN] (6)), or more often by various sources of funding. Some of these neonatal networks are listed in Table 1.

The more clinically oriented networks have made great efforts to develop by consensus a set of standardized indicators based on uniform definitions of perinatal risk or protective factors, frequent neonatal interventions, and significant short- and mid-term outcomes. Among the most widely used are the minimal perinatal dataset developed by the VON (4) and the more extended one used by the NICHD Research Network (3).

All networks maintain databases in which patient and unit identities...
IS GESTATIONAL AGE (GA) A BETTER INDICATOR THAN BIRTH WEIGHT (BW) FOR VERY-LOW-BIRTH-WEIGHT INFANTS (VLBWI) IN 28 DAY NEONATAL MORTALITY?


Background
While foetal maturity, and thus GA is a strong indicator for Neonatal Mortality (NM), it is usually specified for birth weight (BW) subgroups.

Aim
To test if GA is a better indicator than BW for NM rate of VLBWI.

Patients and Methods
Data from 2,759 VLBWI (401 to 1,499 g) cared for in 35 NICUs from 11 European countries participating on EuroNeoNet from 2003 to 2006 was used to design a predictive model.

Three logistic regression models were done including Birth Weight and/or Gestational Age associated to mortality at Day 28. Classification accuracy was given by the area under the ROC curve. Independent models were tested by comparing area under ROC curves, and nested models by testing differences in Deviance.

Results
Descriptives
<table>
<thead>
<tr>
<th></th>
<th>x ± SD</th>
<th>Median [P25;P75]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth Weight (grams)</td>
<td>1,106 ± 264</td>
<td>1,150 [900;1,330]</td>
</tr>
<tr>
<td>Gestational Age (weeks)</td>
<td>29.2 ± 3</td>
<td>29 [27;31]</td>
</tr>
</tbody>
</table>

Apgar 1 Minute: 8.1 ± 1.8 [7;9]
Apgar 5 Minutes: 6.1 ± 2.3 [5;8]

Prenatal Steroids
- Complete: 1,114 (62.1)
- Incomplete: 527 (19.1)
- None: 518 (18.8)

Intubation in DR
- Yes: 968 (35.3)
- No: 1,791 (74.7)

PIVH (Grades III or IV)
- Yes: 109 (8.9)

Cystic PVL
- Yes: 90 (3.3)

SMR adjusted by BW varies from 0.33 to 2.13. There is little difference when adjusting by GA, SMR varies from 0.31 to 2.13. Results for individual Units have not been affected by the adjustment factor except for a slight change in Unit 26.

Individual predictive models for Birth Weight and Gestational Age have been performed. Area under the ROC curve was of 0.799 for the model including both predictors. Individual predictive models for Birth Weight and Gestational Age have been performed. Area under the ROC curve was of 0.785 for the model including Birth Weight and 0.783 for the model including Gestational Age. Although area under the ROC curve for Gestational Age model is bigger than Birth Weight model, differences are not statistically significant (p_value = 0.4).

A model including both predictors was proved to be statistically better than individual models (p_value = 0.05). Area under the curve for this model was of 0.799

Conclusion
BW is a strong indicator of neonatal mortality rate as is GA. The use of both BW and GA, increases significantly the predictive capacity of mortality at Day 28. It is speculated that not only maturity -directly depending on GA-but intrauterine growth- for which BW might be a surrogate- affects neonatal mortality risk.
**Background**

Mortality of VLBWI is considered a good indicator to assess the quality of the perinatal care. Crude Neonatal Mortality (NM) rates of VLBWI vary from hospital to hospital, thus standardisation by birth weight (BW) and/or gestational age (GA) is used to compare outcomes.

**Aim**

To compare 28-Day Standardised Neonatal Mortality of VLBWI cared for at 43 NICU’s from Nicu’s of 11 European countries participating on EuroNeoNet/EuroNeoStat projects.

**Results**

<table>
<thead>
<tr>
<th>Code</th>
<th>N</th>
<th>%</th>
<th>Lower</th>
<th>Upper</th>
<th>BW</th>
<th>GA</th>
<th>BW + GA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>64</td>
<td>17.2</td>
<td>7.7</td>
<td>28.7</td>
<td>16.8</td>
<td>11.1</td>
<td>10.1</td>
</tr>
<tr>
<td>4</td>
<td>48</td>
<td>35.4</td>
<td>21.4</td>
<td>49.5</td>
<td>34.3</td>
<td>31.8</td>
<td>25.2</td>
</tr>
<tr>
<td>5</td>
<td>22</td>
<td>43.0</td>
<td>2.3</td>
<td>0</td>
<td>7</td>
<td>4.4</td>
<td>1.5</td>
</tr>
<tr>
<td>22</td>
<td>74</td>
<td>14.9</td>
<td>8.8</td>
<td>23.2</td>
<td>15.8</td>
<td>13.1</td>
<td>13.5</td>
</tr>
<tr>
<td>4394</td>
<td>16.2</td>
<td>15.1</td>
<td>17.3</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Inter-hospital crude 28-day NM varied from 2.3% (0.7%-7%) to 35.4% (21.4-49.5%). Extremal quotient was of 15.4.

Neither BW nor GA alone or combined decreased NM variability using DS or IS methods (EQ=7.9, EQ=21.7, EQ=12.4 respectively). The number of non predicted deaths adjusting by BW varied from 27 to -41, by GA from 28 to -44, and by BW and GA from 27 to -46.

**Conclusion**

Inter-hospital variability was not accounted for adjusting for GA and/or BW. This might be related to other perinatal risk factors or to variations in clinical practice among NICUs. Anyway, SMR can be used as a tool to compare the effectiveness of interventions implemented to improve the quality of perinatal care given to VLBWI. The adjustment of mortality at day 28 by Prenatal Corticoids exposure, may reduce variability, as shown by decrease of SNM Rate.

* This work was partially supported by a DG SANCO EC Grant (N. 2005 / 116).
Developmental outcome dataset

1. **Time**: At 48 months (plans to 4 yrs)

2. **Dataset items**: “Minimum European Dataset”
   - based on that developed by Ann Johnson (Oxford)
   - Plans to **coordinate with EuroPeristat II**
   - Use definitions by SPCE group

3. **Pilot phase**: H. Cruces, Navarre and Basque country
   - grant by BIOE F

4. **Working group**: lead by M Weindling (Liverpool)
   K Pallás/ J de la Cruz (12 Oct, Madrid)
The future of our project 1

- To submit a EuroNeoStat II project: SANCO ‘08 call
  Community Action Program for Public Health 2009-11

Aims:

1. To increase number of units / regions / countries
2. To develop socio-economic indicators
3. Larger 24-mo follow-up (3 new cohorts)
4. Quality of life at 4 years (2 years cohort)
5. EuroNeoSafe II safety data analysis
Conclusions

- **EuroNeoStat** project in its 2\textsuperscript{nd} year
- All procedures up and running
- Data gathering progressing smoothly
- Interest in the Network is growing
- Number of NICUs joining is increasing
- Contribution to development National Networks
- Dissemination of a patient safety in the NICUs
- Research projects been developed: - Variability
- Sustainability been seek via . Further public funding
  - Affiliation to ESN/ESPR
This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.