



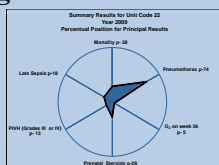
Who are we?



Methods

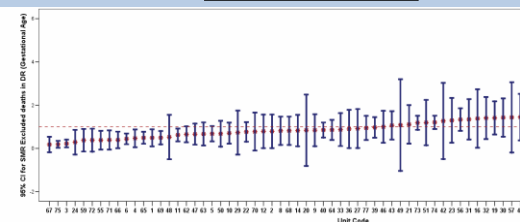
A common perinatal data-set,
based VON (Copyright)
Virtual environment by up-to-date
technology

- 1) Quality-assessment of neonatal care
- 2) Safety initiative ("EuroNeoSafe")
- 3) On-line, interactive continued education
- 4) Promote large RCT's



Main Objective:
To assess Quality of Care
provided to VLBW/VLGA
infants (< 1.500 g or < 32 wks)
born in Europe, to contribute to
the improvement of their health
status and to detect any existing
outcome inequalities.

Mission:
To minimize risks for all those
babies, so their outcome could
the same no matter where they
happen to be born



Participation

>200 NICU's from 17 EU countries
> 6,000 datasets/year, >35,000 total

- 1) Coordinator
- 2) Epidemiologist
- 3) Secretary
- 4) Administrator
- 5) Data Manager
- 6) Biostatistician



What are we aiming to?

From **Benchmarking** to **Quality Improvement** now

- and now to **RCT's**:
- 1) Set-up a platform for RCT's
 - 2) Accreditation of NICUs for RCT
 - 3) Speed-up recruitment of NICUs

A non-pharmacological RCT ongoing
Pharmacological RCTs planed

Spanish Maternal & Child Health and Development Research Network



funded by ISCIII as a Network of Excellence
CAIBER “Spanish Platform for Clinical Trials”

I. Non-pharmacological RCT:

1. Educational intervention to **prevent hospital-acquired infections** in VLBW infants (cluster, step-wedge RCT)
2. Safeguarding the brain of VLBW infants by use of **cerebral oxygenation monitoring** (NIRS)

II. Pharmacological RCT

- 1, ELBW infants RCP with 30 vs. 60% **O₂**
2. Neonates with HIE on Hypothermia plus **Topiramate** vs. placebo
3. **Metmorfin** on childhood obesity effects on metabolic-syndrome-related factors
4. **LMW Heparin** prevent complicati~~os~~ of Eclampsia.
5. Safety & efficacy of **Dobutamine** in VLBW infants with low SVC flow (NeoCirculation 7th RFC funded)