Reviewer’s report

Title: How old are you? Newborn gestational age discriminates neonatal resuscitation practices in the Italian debate.

Version: 1 Date: 3 August 2009

Reviewer: Maria Serenella Pignotti

Reviewer’s report:

The paper presents the actual evolution of the Italian debate on the issue of the best treatment for the Extremely Low Gestational Age neonates.

This is an important problem all over the world. An issue of interest for a broad medial audience as well as for bioethicists, philosophers, jurists, theologises.

Even if the documents presented and discussed in the paper belong to the Italian debate, in my opinion, the reading of the article could be of help for people from other countries as it can add arguments and novel insights to the discussion.

The article is well argued and referenced and it seems well written even if I am not a native English speaker.

However there are some important points that I would like to emphasized and that I hope could be of help for the authors.

First of all, as I wrote to the Editor, for intellectual honesty, I prefer to declare that, as a co-author of the Carta di Firenze, the document the authors are going to criticize, I can’t agree with the authors’ position.

But this does not prevent me to address some suggestions that, from my point of view, can help the authors in improving their paper.

As requested by the editor, I am going to divide my comments into categories.

- Major Compulsory Revisions

a) In the foreword of the CdF is written

“…These [the recommendations] must be considered as suggestions for health operators assisting pregnancies, births, and extremely preterm neonates. Every decision must be taken on the basis of the clinical conditions of the neonate at birth and the local mortality rates. The parents must be consulted after being suitably prepared to face the event they are going through”;

and again “It is therefore necessary to stress how any therapeutic project involving either the initiating or withholding/withdrawing of intensive care must be reviewed and adapted case by case as soon as the clinical conditions of the neonate at birth have been assessed”.

And again, under the subheading “Uncertain gestational age” “in the case of uncertain gestational age, it is vitally important for a neonatologist to make a
clinical assessment of the neonate’s conditions at birth, the obstetric history, and the response to reanimation manoeuvres, in particular, the restoring of the heart rate and skin colour”, as the authors correctly reported at pag 11 of their paper (see http://sites.google.com/site/cartadifirenze/documenti-rilevanti and Pignotti MS et al. Periviable babies: Italian suggestions for the ethical debate. J Mater Fetal Neonat Medicine 2008;21(9):595-598).

Therefore it is not that the CdF “identifies a temporal threshold below which to refuse, a priori, any attempt at resuscitation” (pag 5) …….without taking into account the conditions which have caused such a premature birth….”.

Instead, it is clear that the CdF suggests an individual approach to the very small neonate, although identifying categories of newborns with different prognosis and probability of survival (and then different indications for treatment), based on the gestational age.

Maybe it could be said that the message was not so clear, or that it should be more emphasized. That is possible. If this is the opinion of the authors this must be cleared.

b) pag 6 “the critical point of the CdF, according to experts at the NBC, is the difficulty of establishing truly reliable parameters which would provide the certainty of prognosis at birth. Therefore, the assessment at birth of vital parameters can not have a rigorous prognostic value”

Is this a problem of the CdF or is this a problem of the whole perinatal medicine? The prognostic value of the “clinical conditions” at birth is still debatable. That is why all the Guidelines from other countries, on this issue, are based on the GA more than to recommend to rely on “how the baby looks at birth” (see Pignotti MS et al Pediatrics 2008, Pignotti MS, Archives of disease in childhood Fetal Neonat Ed.2008).

Even if some authors recommend to evaluate the baby’s condition upon delivery (Singh et al 2007, Seri et al. 2008, Byrne S et al 2008 - and the position of the CdF is on this side), early clinical signs have been shown to correlate poorly with survival (Nuffield Council of Bioethics. UK 2006), the clinicians’ ability to predict survival, in recent studies, failed to identify future non-surviving neonates (Meadow et al. 2008) and, lastly, the clinicians’ ability to assess even only “the infant colour” at birth presents wide variations (Byrne S et al 2008).

c) pag 12, 1° line. Gestational age, although imperfect, is still considered the best parameter, indicator of the infant maturation (that means of the survival capacity) and all the existing Guidelines refer to gestational age to recommend behaviours and clinical choices. Studies other than the one reported here (12) must be quoted (Chervenak et al 2007, Allen MC et al 2008), as well as the research the authors report must be quoted (line 6)

d) in the introduction of their work the authors rightly wrote that “the adherence to neonatal resuscitation guidelines is low across Italian tertiary centres.. The practice of and approach to the resuscitation of ELBW infants varies greatly between the centres surveyed, reflecting a paucity of evidence and consequent
uncertainty among clinicians”. That is right. And that is why the CdF was born. Besides, the CdF, in the mind of its authors, had the aim to “guarantee mothers and neonates adequate assistance for the sole purpose to safeguarding them from useless, painful or inefficacious treatment associated with therapeutic aggression”.

It could be important in the discussion to know the authors’ opinion in regard to this aspect. Is now the situation solved? Is it enough to deny guidelines based mainly (but not only) on the main parameter we have in our hands, in a field where the evidence based approach is still just a dream? In these area of uncertainty, without protocol of behaviours for clinicians, the approach to the treatment of a life threatening extremely premature birth, is scientifically and ethically justifiable?

Without any kind of recommendations is the duty of a clinicians easier and safer for the baby, the mother, and himself?

The situation, in Italy, is confused, they said. The lack of protocols and guidelines, even if not perfect, will not expose babies and mothers to futile treatment, uncontrolled experimental therapy? From a clinicians’ point of view is it enough to answer that we do not need “strict guidelines”? Although the last decision on the clinical assessment of the baby belong to the doctor, and this responsibility is the hearth of our intervention, is it enough to defend babies and mother from the danger of futile treatment? The clinicians position is dangerous and asks for a practical answer. I think that this kind of considerations must be drawn in their conclusion.

- Minor Essential Revisions

a) pag 11, 1° line. Quote the reference for the Italian Society of Gynaecology and Obstetrics

b) gestational age, while non considered by the NBC and Italian Superior council of health as an indicative parameter for decision about the initiation of resuscitation, is not debated as a parameter to limit the access to the termination of pregnancy by the same authors (proposed limit 22.3 wks GA)

c) little mistakes in punctuation marks need to be corrected.

- Discretionary Revisions

a) The document Carta di Firenze, was previously quoted in the international literature with its native name (in Italian) maybe the authors could find more appropriate not to rename the document with its translation.

b) Page 7, 3° line: “a treatment which prolongs the life of a disabled person cannot be defined futile simply because it prolongs a life considered by some to be of low quality”. This is not the same abroad. In a lot of countries of the industrialized world it is the opinion of a lot of neonatologists that the future quality of life of a newborn must be taken into account in deciding the best treatment for a very ill neonate. (Verhagen E et al. 2005; Singh J et al. 2004;
AAP 2007, RCPCH 2007). In my opinion it is too easy to consider intensive care always indicated, no matter for the chances of survival (even close to zero) and the hope of intact survival. Some words could be spent on this argument.

c) Page 7, 18° line: “uncertainty about prognosis” or “almost absolute certainty about death”? The authors can explain this issue. What the NBC feels as an “inversion” of the behaviour can be easily explained when clarifying the population of babies we are talking about. The differences between the 22 and the 24 weekers are paramount.

d) Page 8, 9° line. The “full right to therapies”. Do the authors agree with this assumption? The full right to therapies still works if you think that palliative care is a therapy with the same dignity of intensive care and must be considered the right choice, when indicated.

Maria Serenella Pignotti

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have not any financial competing interest.
I am one of the co-author of the Carta di Firenze.