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Italian Committee for Bioethics

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Motion

Inequalities at birth

29th May 2015

Presidenza del Consiglio dei Ministri

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Presidenza del Consiglio dei Ministri

CNB
COMITATO NAZIONALE
PER LA BIOETICA

MOTION

INEQUALITIES IN HEALTHCARE DURING AND AFTER CHILDBIRTH: A NATIONAL EMERGENCY

29 may 2015

The National Bioethics Committee (NBC) sets out to draw the attention of the Institutions and the public opinion to the critical issues related to healthcare at birth to be found in most Italian Regions and which are attributable to the organization of the healthcare system and its facilities. Such critical issues have to be identified, reported, and tackled.

The NBC has already addressed the topic of the issues related to childbirth in various documents, *Coming into the world* (1995), *Pregnancy and childbirth from the bioethical standpoint* (1998), *Premature infants. Bioethical notes* (2008), highlighting, in particular in the Opinion, *Coming into the world*, that the moment of birth, 'influenced by the variables of the social and economic system, requires social, juridical and medical protection, in a context of efficient services.' The recurrence of tragic events, especially in some southern Italian regions, today highlights the existence of serious issues concerning such protection, making it necessary and urgent to seriously reflect on the different levels of responsibility and on the unequal way in which they arise within the different areas.

Indeed, unfair inequalities in medical assistance at birth in our country seriously undermine the respect for the principle of justice in one of its most important and vital expressions, namely the integration of two fundamental human rights, the right to equality and the right to healthcare, only achievable by means of an equitable distribution of healthcare resources. There is no doubt that the issue of unfair differences in the fruition of the right to health is multifaceted and concerns all those living in Italy belonging to all age groups, and the Committee sets out to suitably analyze this problem in a broader perspective, taking into consideration its different, specific aspects[1]. Nevertheless, such a problem has implications involving a great degree of responsibility in the phase immediately following childbirth: the first moments of life are not only characterized by a particular vulnerability, but are also decisive, in either a positive or negative way, for the future of the person. It is increasingly evident that several adult illnesses, as well as many disabilities, can be induced by adverse conditions during the neonatal period and childhood, which therefore, wherever possible, have to be prevented by means of a rational and equal healthcare policy.

It is also necessary to stress both the importance of such prevention measures during the prenatal period and how the issue of inequalities at birth finds its premises in the care of women's health during pregnancy and very often even before this. There is a precise relationship between conditions of socio-cultural hardship and a higher risk of adverse consequences, which can affect the health conditions of both the mother and the fetus. Several studies show how factors that can particularly affect this are the country of origin, schooling, type of job, obstetric precedents, gynecological precedents, general conditions of health, diet, personal hygiene, as well as the type of dwelling. In particular, women originating from foreign countries where the population is forced to migrate have their first check-ups when the pregnancy is already at an advanced stage, do not do any kind of analyses, do not check blood pressure and weight, and often have bad diets both qualitatively and quantitatively. It thus follows that these women fall ill during pregnancy more than the Italians, with pathologies that are either not diagnosed or reported too late: thyroid disorders, diabetes, nephropathies, vitamin deficiencies, hypertension, and pregnancy-related illnesses. Fetal growth restriction is also frequent, as it is often not diagnosed at an early stage.

Effective prevention measures against inequalities at birth should therefore foresee right from the gestation period:

a) the enhancement of counseling services, which should carry out functions of hospitality, cultural promotion, and socio-healthcare integration;

[1] The Committee has already devoted an Opinion to the issue of equity in the field of healthcare (*Bioethical guidelines for equal access to healthcare*, 25 May 2001), and has more recently drawn the attention to the more specific issue of unfair inequalities in the assistance to elderly women (*The living conditions of women in the third and fourth age: bioethical aspects of social healthcare*, 16 July 2010).

b) the setting up of childbirth education classes, where women (especially if foreigners) can be informed about the possibilities to receive appropriate assistance from pregnancy to childbirth and homecoming with the baby;

c) the implementation and simultaneous monitoring of the "birth path" (from 2010 State-Regions Agreement), i.e. taking charge of pregnant women from their first examination, with a program providing for the tests necessary to monitor the health conditions of the mother and fetus.

The NBC is thus aware of the extreme complexity characterizing the issue of inequalities at birth, but by means of this motion it sets out to highlight the aspects strictly related to the organizational shortcomings affecting the period immediately following birth. Indeed, the Committee recognizes that in that period and due to those shortcomings, the right to healthcare is a right that is fulfilled in an unfairly different way depending on the region of birth, which is decided by fate.

Thanks to improved living conditions and medical knowledge in Italy, there has been a significant reduction in infant mortality in recent years, which has reached levels that can be compared to those to be found today in the most developed countries of the western world. Nevertheless, this reduction in infant mortality, of which 70% is represented by neonatal mortality, has not occurred evenly. In the southern regions, it is still higher than in the northern ones by about 30%[2]. The causes of this phenomenon have to be attributed to various factors. In addition to the well-known different weight of economic and social problems, on which it is impossible to dwell here, an element playing a decisive role is the insufficient organization of perinatal therapies and the existence of many little maternity units.

Contrary to what many still believe, the fragmentation of birth centers does not favor the management of emergencies and greatly increases the clinical risk for both the mother and the infant. Very often centers with less than 500 births per year, particularly numerous in southern regions, are not provided with specific equipment and have a staff that is non-specialized and unprepared to cope with emergency situations.

Notwithstanding the provisions of the 2010 State-Regions Agreement, the administrations which established the progressive rationalization/reduction of birth centers within the "birth path" with a number of childbirths lower than 1000/year, find it difficult to close such facilities[3]. Likewise, the same Agreement provided for the setting up, completion, and coming into effect of the maternal assisted transport system and the Newborn Emergency Transport Service (NETS), which nonetheless are not yet available in large areas of the country. Due to the lack of a neonatal transport service in many regions and in large metropolitan areas, there is a significant delay in the beginning of therapies, together with a rise in the risk of death during the neonatal stage or the appearance of neurological damage with disabling consequences in newborns delivered in centers lacking the Neonatal Intensive Care Unit (NICU*).*

It is important that women with high-risk pregnancies give birth in maternity wards equipped with neonatal intensive care units, but it should always be kept in mind that even

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[2] Latest *ISTAT* data, available on the website http://www.istat.it/it/archivio/14562, relating to infant mortality refer to 2012, as mortality data by age are not available for 2013, but only data on birthrate and neonatal mortality. In 2012 there were 242,388 and 182,922 live births respectively in Northern and Southern Italy; deaths within the 1st year of life were 697 and 704 respectively. The infant mortality rate was equal to 2.88 per one thousand live births in the North and equal to 3.85 per one thousand live births in the South. The infant mortality rate in Southern Italy is 33% higher than the one in the North.

[3] Agreement, pursuant to Article 9 of Legislative Decree No. 281 of 28 August 1997, between the Government, the Regions, the Autonomous Provinces of Trento and Bolzano, the Provinces, the Municipalities, and the mountain communities on the document regarding 'Guidelines for the promotion and the improvement of quality, safety, and appropriateness of interventions assisting the birth path and for the reduction of Caesarian sections'. (Rep. acts No. 137/CU) (11A00319);
http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=36591&completo=true.

a normally-progressed pregnancy can unexpectedly get complicated at the moment of birth and engender emergency situations for both the mother and the baby. Hence, each birth center, even if lacking neonatal intensive care units, needs to be able to deal with emergency situations while waiting for transfer to an equipped center.

It should also be noted that NICUs, which amount to a higher number than the recommended standards, are not provided with an equally high number of actually available beds. This is often due to shortages in medical staff and/or nurses or to a lack of space and valid equipment from a technological point of view.

It is a fact that the regions with the most critical healthcare situations are those subject to recovery plans from the regional economic deficit, in which it is not possible to hire new staff or even to replace those retiring. Due to the lack of beds in NICUs, very often even when very premature babies are born in a properly equipped center, they cannot be treated in the same hospital and have to be transferred to another center where a bed in the NICU is available[4]. Such transfers can have serious consequences for the health of the baby, especially for the most critical newborns.

Without an increased efficiency of the NICUs and an improved organization of the perinatal network, neonatal mortality rates in the southern regions cannot be lowered. In the light of the above-mentioned critical issues, it seems appropriate to highlight how, from an ethical perspective, it is inadmissible that the compliance with the different parameters imposed by the recovery plans can impact so heavily on the right to health.

Another inequality in the provision of healthcare to newborns relates to the implementation of the Expanded Newborn Screening, which enables the early diagnosis of more than 40 rare pathologies, many of which are disabling. Today this test is carried out only in some regions of Italy[5], but recent legislative interventions (2014 Stability Law) are expected to solve this problem in the near future. It is also desirable that all birth centers are able to perform the audiologic screening, aimed at an early identification of hypoacusis and deafness, as well as the ophthalmological screening for an early diagnosis of visual abnormalities.

The NBC therefore considers it urgent to draw the attention of the Government, the Regions, and the Autonomous Provinces to the need for a concrete implementation throughout the national territory of the diagnostic-therapeutic-healthcare paths established for birth[6], for a check and a periodic monitoring of the criteria characterizing such paths, as well as for effective and decisive interventions where the regions encounter difficulties in the provision of neonatal medical assistance. As provided for by Art. 117 of the Italian Constitution, essential levels of services relating to civil and social rights have to be guaranteed throughout the national territory and it is unacceptable that the respect for budget balances negatively affects the right to health. Hence, it is necessary to stop the trend of differentiation in healthcare provision between the different regions and it is essential

[4] In the Lazio Region, in 2014, 101 newborns were transferred, due to a lack of beds, from a III level center, i.e. an NICU, to another NICU, of which 96 babies were preterm and 25 had a gestational age of less than 28 weeks (Lazio Region, Directorate of Health Care, Health and Social-Health Care Integration. Neonatal Transport in the Lazio Region 2004-2014);
http://www.regione.lazio.it/binary/rl_sanita/tbl_contenuti/Trasporti_neonatali_2004_2014.pdf.

[5] From the consultation of the technical report on neonatal screening programs in Italy, drafted in 2013 by the Italian Society for the study of hereditary metabolic diseases and neonatal screening, it comes to light that national coverage is total for hyperphenylalaninemia and congenital hypothyroidism, stable at about 80% for cystic fibrosis and 30% for expanded screening to metabolic diseases;
(http://www.simmesn.it/it/documents/rt_screening/rt_screening_2013.pdf).

[6] Agreement between the Government, the Regions, and the Autonomous Provinces of Trento and Bolzano, the Provinces, the Municipalities, and the mountain communities on the document regarding 'Guidelines for the promotion and the improvement of quality, safety, and appropriateness of interventions assisting the birth path and for the reduction of Caesarian sections' (16 December 2010).

to integrate them, in order to guarantee everyone the right to “the enjoyment of the highest attainable standard of health” from the moment of birth, as the safeguard of health is a “fundamental right of the individual and a collective interest” (Art. 24, paragraph 1 of the 1989 UN Convention on the Rights of the Child and Art. 32 of the Italian Constitution).

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The document was drafted by Prof. Mario De Curtis, with the contribution of Prof. Marianna Gensabella.

The document, discussed within the plenary, was voted and approved unanimously by those present, Profs. Luisella Battaglia, Carlo Caltagirone, Stefano Canestrari, Carlo Casonato, Francesco D’Agostino, Lorenzo d’Avack, Antonio Da Re, Mario De Curtis, Carlo Flamigni, Silvio Garattini, Marianna Gensabella, Demetrio Neri, Andrea Nicolussi, Laura Palazzani, Massimo Sargiacomo, Monica Toraldo di Francia, Grazia Zuffa.

The ex Officio members who joined are the following: Drs. Maurizio Benato, Carla Bernasconi, Carlo Petrini.

Among those who did not attend the plenary session, the following members adhere to the Declaration: Profs. Salvatore Amato, Rodolfo Proietti.

Personal remark

A personal remark by Prof. Cinzia Caporale

The writer of this remark adheres to the idea expressed in the Motion according to which it is ethically very relevant to tackle the inequalities in the enjoyment of the right to health which persist in different areas of the country. Such inequalities are increasing among the elderly, but certainly assume a very special significance in the stages immediately following birth, as rightly stated by the Drafters.

However, with regard to the specific contents of the Motion, the writer wishes to highlight as follows:

1. With regard to infant mortality rates, Italy has lower levels than those of countries like France, Germany, Great Britain, Canada, and the United States and, anyway, has rates which place it among the best countries worldwide in the most reliable international rankings.
2. According to *ISTAT* data, there has been a continuous decrease in infant mortality rates since the 1950s until today throughout the country, with higher percentage decreases in Southern Italy. For example, from 1951 to 2011, the infant mortality rate decreased by about 17 times in the North and about 22 times in the southern Regions.
3. Notwithstanding the occurrence of more significant improvements in the South, the data still report a higher level of infant mortality in this area. However, considering also the absolute numbers illustrated in the Motion (a difference of 7 deaths per year between the North and southern Regions out of a total of 1,401 deaths per 425,310 live births), the interpretation of the data requires a great deal of caution because, as for all socio-healthcare phenomena, there are undoubtedly multiple underlying causes which should be deeply analyzed in order to understand their single and aggregated effects and to assess which of them proves 'decisive' within the different contexts. As suggested also by the Motion – though in a non-satisfactory way, according to the writer – there are indeed several endogenous and exogenous factors affecting the occurrence of different risk situations at the moment of birth and in the first year of life: medical assistance is just one of the determining causes. Not by chance, infant mortality is normally considered as an indicator of the persistence of social problems that can be tackled by means of large-scale preventive interventions and actions. In the writer's opinion, it is therefore not possible to adhere to the following statement laid down in the Motion: "Without an enhancement of the NICUs and an improved organization of the perinatal network, neonatal mortality rates in southern Regions cannot be lowered."
4. With regard to the general inequalities between regions and macro-areas of the country, in the case of healthcare services, there has been a significant improvement of outcome indicators over time, and specifically in the last ten years. This has been the case for both the national average and, particularly starting from the middle of the last decade, for the southern regions specifically. As a matter of fact, available indicators report a significant improvement in national average data and a process of convergence in service standards guaranteed in the different areas, with a decrease in situations of technical inefficiency. For example, the rationalization of the offer of healthcare services, which came about following the introduction of the Recovery Plans in 2006, has accelerated the shutdown process of marginal facilities throughout the country, concentrating the birth centers within a relatively limited number of units and increasing the conditions of technical efficiency and levels of effectiveness, assessed on the basis of outcome indicators. Such improvements have to be mentioned and underlined, albeit some critical issues persist and need to be overcome, particularly in the southern regions.
5. Overall, available data do not support the argument according to which the 2001 federal reform would have brought about an increase in the differences concerning

healthcare outcomes among regions. Conversely, the constant monitoring of the adequacy of expense levels with respect to efficient benchmarks has introduced a permanent pressure towards the improvement of both organizational solutions and service levels. In other words, once the homogeneity of the criteria defining the essential levels of healthcare services was ensured, the existence of a differentiation between areas has represented a positive push towards the improvement of service levels and standards of technical efficiency. In any case, in the writer's opinion, the evaluation of the Recovery Plans and the specific economic aspects regarding healthcare policies falls outside the competences of the National Bioethics Committee.

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