www.jpnim.com Open Access eISSN: 2281-0692
Journal of Pediatric and Neonatal Individualized Medicine 2014;3(2):e030257
doi: 10.7363/030257
Received: 2014 Sept 28; accepted: 2014 Oct 01; published online: 2014 Oct 08

Review

Birth in Italy between outcomes, appropriateness and responsibility

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Proceedings

Proceedings of the 10th International Workshop on Neonatology · Cagliari (Italy) · October 22nd-25th, 2014
The last ten years, the next ten years in Neonatology
Guest Editors: Vassilios Fanos, Michele Mussap, Gavino Faa, Apostolos Papageorgiou

Abstract

Maternal mortality and morbidity related to perinatal events are increasingly rare in advanced countries. Maternal death events represent an indicator of the overall health and development conditions of a country. In Italy, similarly to other industrialized countries, the maternal mortality ratio has been approximately 3 cases per 100,000 live births. However, recently, it has been measured as 11 cases per 100,000 live births, with a severe maternal morbidity rate of 2‰. The neonatal mortality rate has been, instead, constant at approximately 2.4‰ live births, with a rate of childhood cerebral palsy of 2‰. The incidence of caesarean section in Italy is 38% on average. It is the highest in Europe, with significant regional differences. The higher incidence is observed in the birth centres of South-Italy and in those with a fewer number of deliveries.

The whole "birth pathway" should be organized and planned on a regional basis according to the models of organizational network of perinatal care by Hub & Spoke and according to the principles ratified by the GL (guidelines) on the Charter of Services N. 2/95, such as: equity, accountability, participation, quality and safety of care, humanization.

However, an obstacle to the implementation of this program is represented by the exponential and manufactured increase of medico-legal controversies (+ 250% of complaints over the last 15 years) with over 98% of acquittal in favour of the doctors for the Supreme Court.

This issue discredits the entire medical profession and is responsible for the recourse to defensive medicine which drains each year 10bn euros. Therefore, a joined action among the legislature, the professional associations and the civil society is needed.

Keywords

Birth event, maternal mortality and morbidity, caesarean section, network of perinatal care, defensive medicine.

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How to cite

Ettore G, Murolo G, Ferrara L, Ettore C. Birth in Italy between outcomes, appropriateness and responsibility. J Pediatr Neonat Individual Med. 2014;3(2):e030257. doi: 10.7363/030257.

Introduction

Maternal mortality and morbidity related to the perinatal care represents a quality indicator for any health care system. Prenatal, peripartum and postnatal periods include the leading cause of women's hospitalization in Italy, with a significant variability among the regions [1]. A similar variability is observed for the Infant Mortality Rate, which measures the mortality in the first year of life; it was 3.48/1,000 live births in 2009. Over the past 10 years, this rate has progressively decreased over the whole Italian territory, although in the last few years a slowdown of this trend has been observed.

Moreover, the Neonatal Mortality Rate, indicating the mortality within the first month of life, still accounts for over 70% of the infant mortality.

The Agreement between State and Regions, made on the 16th December 2010, aims to create a national program, based on ten lines of shared actions, for the promotion and improvement of the quality, safety and appropriateness of "birth pathways".

A large number of deliveries in Italy still occur in hospitals with less than 500 deliveries/year, with a significant variability observed across the regions. Caesarean Section Rate is also widely different across the Italian regions.

In order to contrast this discrepancy, the Agreement between State and Regions set in at least 1,000 deliveries/year the standard for the maintenance of a maternal hospital.

The main objectives of the Agreement are:

- reduction of the number of maternal hospitals with less than 1,000 deliveries/year; the only exception of keeping centres with a lower number of deliveries, but not below 500 births/year, may be justified for specific geographic areas, related to maternal and neonatal transport issues;
- rationalization of the use of caesarean section.

Outcome

According to the scheme of Avedis Donabedian [2, 3], the quality of care has three main components:

1. structure, i.e. characteristics and context in which care is delivered, in terms of resources and organization (equity, guarantee of access to health care, organization and coordination, construction, technology, financial resources, human resources, in terms of number, expertise, organization and workload of the staff, diagnostic services and therapy...);
2. process, i.e. the modality of access to health care and the performances actually offered (adherence to the guidelines, effective communication, adequate skills...);
3. results (outcome), i.e. the real effect on the health status of patients and population. The Improvement of the health status includes also the level of information and satisfaction of the patient.

The statement of Donabedian, although dates back to the last century, is still valid, and universally accepted by the scientific community. It highlights how the overall quality of health care depends on the convergence of its three components. The quality factors of the structure have a basic role for the improvement of the health care process; and the development of a good health care process is fundamental in determining a successful outcome.

Even if late comparing to the UK system, recently the Italian health system has started to use methods for comparing the outcome of different health professionals and structures. Informative sources (as SDO [*scheda di dimissione ospedaliera*, i.e. hospitalization discharge chart], CEDAP [*certificato di assistenza al parto*, i.e. certificate of birth attendance], etc.), traditionally used for bureaucratic-administrative purposes, represent one of the instrument to evaluate the quality and safety of care [4].

The Legislative Decree 158/2012 stipulates that each region has to promote a system aimed to monitoring the health activities. The purpose is verifying the performance quality of each care Unit, whether public or accredited private, in cooperation with the national program for the evaluation of outcomes, created by Agenas (National Agency for Regional Health Services) [5]. The National Programme Outcomes (PNE:

Programma Nazionale Esiti), within the Italian National Health System (SSN, *Sistema Sanitario Nazionale*), is aimed to the assessment of health care interventions; it uses observational (non-experimental) protocols to evaluate the outcomes of health interventions and treatments. The PNE also includes indicators of maternal-child area, validated and recognized by the international literature, used for the comparison of performances delivered by public and private structures. The main indicators are presented below.

Deliveries by primary caesarean section

The "Rate of deliveries by primary caesarean section" is one of the leading quality indicator internationally used. Hospitals and health systems are often compared according to this indicator, with the assumption that lower values reflect a more appropriate clinical practice. The rate measures the number of deliveries by caesarean section in women without a previous hysterotomy, and the higher this rate is, the more likely (over 95%) is to perform caesarean section for the following deliveries.

Several studies suggest that a high number of caesarean sections are done for "non-medical indications". The comparison between different hospitals may moreover be distorted by the different distribution of risk factors for caesarean section. Several clinical situations, such as anomalies of placental or cord insertion, fetal distress, HIV infection, fetal-pelvic disproportion, represent a correct indication to perform a caesarean section; also discrepancies in socio-demographic aspects or in the facility of access to high-risk pregnancies Units increase the likelihood of a caesarean section.

Maternal complications during peripartum and postnatal period

The acute severe maternal morbidity ("near miss") includes serious and potentially fatal obstetric complications. It represents a valid indicator of the quality of midwifery care; it has recently acquired a greater value, particularly in socially advanced countries with low mortality maternal ratios. The Severe Maternal Morbidity Rate (SMMR), i.e. the ratio between the number of "near misses" and the total number of deliveries, is widely used as a measure of maternal outcomes. The extreme heterogeneity of inclusion criteria and classification of "near misses" limits, however, the use of this indicator to compare hospitals of different countries.

According to the surveys of WHO, the prevalence of severe maternal morbidity varies internationally depending on the definition of "near misses", with a range of 0.01% to 8.2%.

Two different indicators are commonly used to measure the serious maternal complications during peripartum and puerperium:

- serious maternal complications during delivery and puerperium, i.e. the proportion of serious maternal complications occurred within 42 days after delivery; it is considered to be consequent to the hospitalization;
- pregnancy complications observed during delivery and puerperium, i.e. the proportion of serious maternal complications occurred within 42 days after delivery; it is considered as responsibility of the area of residence.

In both cases, for the definition of severe maternal complications, both clinical criteria, and criteria based on specific procedures and interventions were used.

Another indicator is the "Readmissions to hospital 42 days after hospitalization for childbirth", with the objective to evaluate the frequency of re-hospitalization following delivery. The measurement of these indicators might help to highlight any differences in the quality of care among different regions.

Appropriateness and quality standards and safety

In line with the objectives set by the Agreement between State and Regions, in 2012, nationally Agenas and the major scientific societies [1] prepared a set of standards of behaviour, inspired by the Joint Commission International (JCI) method, which aims to become a reference model for all professional actors involved in the "birth pathway".

In the manual made by Agenas it is written:

"This document is meant to represent a tool allowing professionals and users to make safer the activities carried out within the birth centers". The document proposes the identification of a series of shared standards and criteria, which are applicable to all specific situations.

The standards of quality and safety are described in a unique document including the following areas:

A. competence of staff, standardization of clinical practice and safety of both mother and baby;
B. maternal and newborn rights of health education and information;
C. evaluation of needs and planning of care;
D. labour and delivery;
E. management and safe use of medications;

F. prophylaxis and control of healthcare-associated infections;
G. management of clinical records and correspondence;
H. leadership of the birth centre;
I. environmental safety;
J. measurement and improvement of performances;
K. establishment of measures.

The document is aimed to evaluate each birth centre, comprehensive of labour room, delivery room, operative theatre for caesarean sections and "neonatal island"; it is directed to all professionals working in the birth centres of the SSN: obstetricians, midwives, nurses, anesthesiologists, pediatricians and neonatologists.

The evaluation is referred to labour and delivery, whose management in security involves the informations concerning the prenatal period and the provision of informations for the management of mother and newborn in puerperium and during the first days of life.

On the basis of this manual, the Sicilian Region has started a regional project for the improvement of the quality of birth centers through the application of the manual and achievement of the expected safety standards.

Responsibility

Quality and safety of care are important aspects of health policy and have a high social impact; they are structural components of the LEA (*livelli essenziali di assistenza*, essential levels of assistance) and are shared by European policies.

Patient safety is guaranteed through the identification, the analysis and the management of possible clinical risks and accidents. The general principles for the management of clinical risk are: the accountability of leadership, promotion of working as a team, proactive attitude and promotion of continuous training [6, 7].

The cultural progress has determined and still determines both improvement and specialization of health care, and an increase in expectations regarding health capacity and prospect for a quick recovery.

The exponential increase in medico-legal controversies is becoming a characteristic of all culturally, democratically and economically advanced countries. The spread of the insurance benefits also have an impact on the increased number of controversies.

A key element of the quality of care is represented by the specific skills and expertise of the staff. The Ministry of Health defines "competence" as the "implementation" of behaviours that allow a professional to perform safely and effectively every procedure, achieving outcomes consistent with best practices or with defined standards of quality. The judgment of competence include: knowledge, clinical skills, and also communication skills, good personal conduct and professional ethics.

According to the Standard SQE.10 (JCI), every hospital needs a specific and evidence-based standardized procedure to authorize physicians to admit and treat patients and provide clinical performance according to their qualifications.

The decisions of a health care organization should be balanced according to the resources available, to promote the quality of its health services, to define the updated clinical skills of the physicians and to determine the clinical performances that each physician is authorized to perform: this process is called "assignment of privileges".

Conclusions

The changing process has to consider three basic elements, in order to improve the quality and the safety of maternal hospitals:

a. measurement of outcomes, in order to reduce the variability among different regions and structures of our country;
b. proposal of interventions of proven effectiveness, taking into account the preferences of the patient;
c. joined application of the process by political, managerial and professional systems.

Evaluation of outcome, appropriateness and responsibility are key elements around which professionals, managers, administrators, and policy-makers have to work synergistically to share decisions ("Shared decision making").

The "birth event" is an indicator of the overall quality and functionality of any health care system; therefore the quality and safety of perinatal care represent a fundamental part of the LEA.

Declaration of interest

The Authors declare that there is no conflict of interest.

References

1. Italian Health Service. Programma nazionale valutazione esiti (PNE). 2013.
2. Donabedian A. Evaluating the quality of medical care. Milbank Quart. 2005;83:691-729.

3. Donabedian A. The quality of care. How can it be assessed? JAMA. 1988;260:1743-48.
4. Italian Health Service. Certificato di assistenza al parto (CEDAP); analisi dell'evento nascita. 2010.
5. Agenas (National Agency for Regional Health Services). Gli standard per la valutazione dei punti nascita. 2012.
6. Aleo S, DeMatteis R, Vecchio G. Le responsabilità in ambito sanitario. Padua: CEDAM, 2014.
7. Ettore G, Donzelli G, Murolo G, Zanini R. Competenze dei professionisti e responsabilità delle organizzazioni sanitarie. In: Aleo S (Ed.). Le responsabilità in ambito sanitario. Padua: CEDAM; 2014, pp. 1347-71.