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Regulation of treatment of infants at the edge of viability in Italy: the role of the medical profession?

Maria Serenella Pignotti,1 Sofia Moratti2

ABSTRACT
In the last few years there has been intense debate in Italy on administration of life-prolonging treatment to premature babies at the edge of viability. In 2006, a group of experts based in Florence drafted recommendations known as Carta di Firenze (CdF) for responsible use of intensive care for premature infants between 22 and 25 weeks of gestational age (GA). The CdF was later endorsed by several medicoprofessional associations, but was followed by recommendations by the Ministry of Health mandating resuscitation for all premature babies regardless of GA and parental consent. Recent statements from medicoprofessional bodies seem to show that the ‘always resuscitate rule’ is not supported by many Italian doctors. We argue that ethically sensitive issues in medicine should be regulated with, and not against, the medical profession and its representative bodies.

INTRODUCTION
In the last decade, guidelines on administration of life-prolonging treatment of premature infants at the edge of viability have been issued in several countries.1 2 There is general consensus that life-prolonging treatment, while being almost always medically appropriate in infants of 25 weeks of gestational age (wks-GA) and above, should be withheld in neonates of less than 23 wks-GA on grounds of ‘medical futility’.3 4 If the infant is between 23 and 24 wks-GA, parental wishes, together with the clinical history of the baby at birth, should guide the doctor’s decision.1–4 The debate is developing in Italy too, and we have recently reported our concern about the governmental and political interference in medical practice.5 Foreign colleagues with various social, political and religious backgrounds seem to share this concern.6 The aim of this paper is to stimulate reflection on the regulation of perinatal care at an extremely preterm gestational age and on the undesirability of political interference in the professional autonomy of doctors.

THE CARTA DI FIRENZE: RECOMMENDATIONS FOR RESPONSIBLE USE OF INTENSIVE CARE FOR EXTREMELY PREMATURE BABIES
In 2002, in the city of Florence, doctors and legal experts joined forces and formed a working group. The working group was not appointed, but created on its members’ initiative. Their goals were to review the literature on the outcome of infants of uncertain viability as defined above 7 and to issue treatment recommendations, in order to overcome a situation characterised by lack of regulation and significant differences in medical attitudes and behaviour among hospitals and healthcare professionals.5 9 As no national data on survival of babies at the edge of viability were available at the time, the group referred to European studies10–16 and reviewed international guidelines and practice recommendations.1 2 Finally, the group issued a consensus statement known as Carta di Firenze (CdF).17 18 The contents of the document are summarised below.

The role of gestational age (GA) in treatment decisions
GA is a crucial factor for estimating an infant’s prognosis.19 20 This still holds, although recent studies have shown that other factors (including birth weight, twin birth, intrauterine growth retardation and gender) might also be relevant in making prognostic predictions.21 GA can be established from the last menstrual date; if that is not known, ultrasound measurements may be of help. In rich countries, it is common to plan pregnancies, and GA is nearly always known and considered reliable.16 22

Practical suggestions for neonatal and maternal treatment
The CdF provides that decision-making for the management of high-risk pregnancies up to 22 wks-GA should be exclusively based on the health of the mother. Once delivered, the baby should receive comfort care and not life-prolonging treatment. In the case of a 25-wk-GA pregnancy, caesarean section upon fetal indication is recommended. The baby’s viability should be evaluated at birth, and resuscitation undertaken only if the baby shows vital capacities and with the parents’ approval or request. In the case of serious compromise of the baby’s clinical condition, the doctor, in consultation with the parents, should consider abstention from (further) life-prolonging treatment, while maintaining comfort care. For a 24-wk-GA pregnancy, caesarean section upon fetal indication can sometimes be considered. Life-sustaining treatment is usually indicated and can be administered on the basis of the baby’s clinical condition. For a pregnancy of 25 wks-GA or more, caesarean section upon fetal indication is recommended. Once delivered, the baby should receive resuscitation and intensive care, unless its clinical condition is so poor that survival does not seem possible.17 18

Inclusion of the parents in the decision-making process
The CdF provides that parents must always be included in the decision-making process. The doctor
Aftercare
After a decision not to resuscitate, the baby must receive adequate comfort care, and much effort must be made to support the family through the bereavement process. After a decision to treat, considering the high incidence of cognitive and developmental impairments in premature infants, a strict follow-up programme must be provided for the child and family. The programme should include adequate learning support during early school years.

THE INTRODUCTION OF THE ‘ALWAYS RESUSCITATE RULE’ BY THE MINISTRY OF HEALTH
The CdF was endorsed by several medical associations, by the Regional Bioethics Committee of Tuscany (the region containing Florence) and by a committee of experts appointed by the Minister of Health. Therefore, the expectation was that it would be used as a basis for developing guidelines at the national level. However, rather unexpectedly, following a debate on the CdF in the media, the Health Council and the National Bioethics Committee (both advisory bodies to the government, appointed by the government itself at the beginning of its mandate) issued statements to the effect that every premature infant should receive resuscitation at birth irrespective of GA and parental opposition. Confronted with opposite statements by different bodies, the Minister of Health eventually chose to support the always resuscitate rule. This case shows the polarization that the debate on end-of-life issues has reached in Italian politics and society.

WHERE WILL THE ALWAYS RESUSCITATE RULE LEAD?
There are arguments against the always resuscitate rule. Intensive care can in certain cases do more harm than good, and should be administered responsibly—that is, not indiscriminately. Administering intensive care amounts to invading the physical integrity of a human being. Such an invasion is justified only if beneficial. Moreover, in line with international literature and practice guidelines, GA and parental consent are crucial factors in the decision-making process, and should not be overlooked.

‘Life-saving treatment’ or ‘experimentation’?
There is some controversy in the medical literature on the appropriateness of administration of intensive care to extremely premature neonates. Some maintain that it amounts to experimentation on human beings and should be regulated as such, only if beneficial. Moreover, in line with international literature and practice guidelines, GA and parental consent are crucial factors in the decision-making process, and should not be overlooked.

Whose child?
Failure to establish a good relationship with the parents could be regarded as a professional failure in itself. Encouraging doctors to exclude parents from the decision-making process can have disastrous results. Unable to deal with the consequences of treatment decisions that have in fact been forced upon them, the parents might find it difficult to keep visiting their baby regularly in hospital, or to maintain contact with the neonatal care specialists altogether. The feeling of being excluded from decisions about the care of their baby does not help them to overcome the feelings of guilt and impotence that often accompany the birth of an extremely premature child. We acknowledge that, in very rare, exceptional cases, it is possible that the parental position is in contrast with the best interests of the infant. In such a case, the duty of the doctors is to act for the infant’s benefit, and it is certainly desirable that guidelines be issued for decision-making in cases of disagreement between the parents and medical staff. However, such a situation is an exception. A regulation of the decision-making process that systematically presumes parents’ incompetence to make decisions for their children is unfair to the parents, in contrast with guidelines from scientific societies and expert opinion, and likely to increase the growing amount of litigation in the healthcare setting.

Reactions from the medical profession
The legal consequences for doctors of the introduction of the always resuscitate rule are, at present, not entirely clear. It is a ministerial practice recommendation and, as such, in case of litigation, will be taken seriously by the judge. However, the systematic exclusion of the parents from the decision-making process appears not to be consistent with the regulation of parental custody in Italian law. The medical profession voiced its views. In June 2008, various major Italian medical associations together with some 120 doctors wrote an open letter to the Minister of Health, the President of the Health Council and the President of the National Bioethics Committee, arguing that the always resuscitate rule is against the interests of babies at the edge of viability and their families and puts doctors in a very difficult position. In October 2008, the Italian College of Physicians issued a position statement arguing that the always resuscitate rule contrasts with the Italian Code of Medical Ethics. However, the position statement was not taken into consideration and the open letter remains to this date unanswered.

CONCLUSIONS
Technical advances in medicine and the increased ethical consciousness among patients, healthcare professionals and in society make it necessary to issue an increasing amount of regulation over administration of aggressive life-prolonging treatment. The process of regulation should take into account recent and reliable data from medical research and national and international medicoprofessional protocols. The recommendations by the Italian Ministry of Health do not help doctors and parents to deal with difficult ethical decisions concerning administration of life-prolonging treatment in premature babies at the edge of viability, merely recommending resuscitation for every baby in the delivery room, thus postponing the decision to the neonatal intensive care unit setting. Paradoxically, the new regulation makes decision-making more problematic and potentially conflict-laden than it used to be in the past, when any such recommendations were absent at the national level. Furthermore, the new regulation stopped a development (the CdF) that might be regarded as more consistent with the
interest of babies (and parents) and with doctors’ professional autonomy. It can be argued that the introduction of the always resuscitate rule amounts to an invasion of doctors’ professional autonomy, and mandates what amounts to medical experimentation in violation of Italian law and international practice guidelines.

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