

Ethically complex decisions in the neonatal intensive care unit: impact of the new French legislation on attitudes and practices of physicians and nurses.

Micheline Garel, Laurence Caeymaex, François Goffinet, Marina Cuttini,
Monique Kaminski

► **To cite this version:**

Micheline Garel, Laurence Caeymaex, François Goffinet, Marina Cuttini, Monique Kaminski. Ethically complex decisions in the neonatal intensive care unit: impact of the new French legislation on attitudes and practices of physicians and nurses.. *Journal of Medical Ethics*, BMJ Publishing Group, 2011, 37 (4), pp.240-3. <10.1136/jme.2010.038356>. <inserm-00578566>

HAL Id: inserm-00578566

<http://www.hal.inserm.fr/inserm-00578566>

Submitted on 21 Sep 2011

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

22/03/11

ETHICALLY COMPLEX DECISIONS IN THE NICU: IMPACT OF THE NEW FRENCH
LEGISLATION ON ATTITUDES AND PRACTICES OF PHYSICIANS AND NURSES

Micheline Garel*, Laurence Caeymaex**, François Goffinet*, Marina Cuttini***, Monique
Kaminski*.

*Inserm, UMR S953, Epidemiological Research Unit on Perinatal Health and Women's and
Children's Health, F-94807, Villejuif, France.

**Service de médecine néonatale, CHU Port Royal-Cochin, Paris, France, Department of Research on
Ethics, EA 1610, Etudes sur les sciences et les techniques, Paris Sud 11 University

***Unit of Epidemiology, Pediatric Hospital Bambino Gesù, Roma, Italy.

Corresponding author :
Micheline Garel
INSERM U 953, 16 avenue Paul Vaillant-Couturier
94807 Villejuif Cedex, France

E-mail address: micheline.garel@inserm.fr
Tel :+33 1 45 59 50 87
Fax +33 1 45 59 50 89

KEY-WORDS: neonatal intensive care, ethical dilemmas, legislation, professionals, EURONIC,
qualitative research

Word count : 3 119

22/03/11

The Corresponding Author has the right to grant on behalf of all authors and does grant on behalf of all authors, an exclusive licence (or non exclusive for government employees) on a worldwide basis to the BMJ Publishing Group Ltd and its Licensees to permit this article (if accepted) to be published in JME and any other BMJPGJ products to exploit all subsidiary rights, as set out in our licence (<http://group.bmj.com/products/journals/instructions-for-authors/licence-forms>)."

The authors declare no conflict of interest.

In the last ten years, the French National Consultative Committee on Ethics for Life Sciences and Health (CCNE) and the French Federation of Neonatologists-Pediatricians have issued various recommendations and guidelines about neonatal intensive care and decisions concerning treatment withdrawal. These guidelines have called for more parental involvement in decision-making; concern has also been expressed about overtreatment at birth and active euthanasia.[1] During the same period the legislature enacted two laws, neither specific to neonatal care : L. 2002-303 (dated March 4, 2002) on patients' rights, which affirmed the principle of patient autonomy, and L. 2005-370 (dated April 22, 2005), known as the Leonetti's law, concerning patients' rights at the end of life. The latter prohibits unreasonable obstinacy in investigations and treatment and authorises the withholding or withdrawal of treatments when they "appear useless, disproportionate or without any effect besides maintaining life artificially". When life support treatment is discontinued, palliative care and pain relief must be provided and sedatives or analgesics administered, even at the risk of hastening death. The new laws also stipulate that the parents of a minor patient must be informed and give their opinion but that their consent is not necessary: when a decision to forego life-sustaining treatment is at stake : in this case, the medical decision prevails over any parental rights. In any case, decisions for incompetent patients, including minors, must be preceded by a collegial procedure that includes consultation with the health care team, at least one external consultant, a trusted person appointed by the patient (if any), and the family. Active euthanasia is always forbidden.[1]

These new laws and guidelines apply to situations and practices such as those reported in the EURONIC study. EURONIC was conducted in 1996-1997 in 11 European countries to describe the attitudes and self-reported practices of physicians and nurses working in NICU relative to ethically complex decisions. The EURONIC study consisted of four parts: a survey of NICU policies,[2] a qualitative study carried out in 1997, in Italy and in France only, based on semi-structured interviews with physicians and nurses,[3] a quantitative study by anonymous questionnaires exploring the attitudes and self-reported practices of these categories of professionals across Europe,[4,5] and a review of current legislation and official guidelines.[6] The main results of the qualitative study showed that French physicians sometimes made decisions about treatment withdrawal and even active

termination of life and that they did not explicitly involve parents in decision-making.[3] The quantitative questionnaire survey showed that French physicians, compared with their European colleagues, were among the least likely to report decisions to withhold treatment and among the most likely to describe the administration of analgesics or sedatives, despite the risk of hastening death.[4,5] French physicians were also more likely to report having been involved at least once, by themselves or together with colleagues, in a decision to administer drugs with the purpose of ending life. Only in the Netherlands were such practices reported at similar frequencies. Finally, France was the country where parents appeared least directly and explicitly involved in decisions about the withholding or withdrawal of treatment.

Since the publication of the EURONIC data, several European countries have also implemented new guidelines or enacted new legislation.[1,7-9] Have these new frameworks affected the attitudes and practices reported by NICU professionals ? The absence of publications assessing possible changes in behaviours led us to study this issue. Our first objective was to describe, as in the French EURONIC qualitative study, the attitudes and practices reported by French NICU physicians and nurses when faced with ethical dilemmas. Our second objective was to identify possible differences between these reports and the results obtained before the changes in the French legislation.

Population and methods

The recruitment sites were the same as in the EURONIC qualitative study: two level III NICUs, one in Paris (A) and one in the Centre region (B). A third centre (C) in the south of France was added to increase the sample size and geographical diversity.

As in the first study, all full-time physicians working at the time of the survey, excluding interns and part-time consultants, and every other nurse on the alphabetical list of staff were invited to participate. The qualitative method was chosen, both to meet our objective of comparison and to be able to explore a wide range of attitudes, personal feelings, specific experiences, concerns and contradictions.[2] The semi-structured interviews, which lasted approximately 60 minutes, used a framework very similar to that of the EURONIC qualitative study and were conducted by the same investigator (MG). As in the previous study, content analysis was used to identify the recurring themes emerging from the interviews. The procedure, based on phenomenological approach, took place in four-steps: immersion

in the raw data, identifying units of meaning, abstracting the contents of individual units of meaning, and summarising their importance.[10] The analysis also allowed to examine the relationship between the staff's answers and their demographic and professional characteristics. Confidentiality was guaranteed for the names of participants and their workplace. Between February and October 2007, 19 physicians (4 in A, 8 in B, and 7 in C) and 17 nurses (4 in A, 6 in B and 7 in C) were interviewed. One of the eligible physicians was on maternity leave. One physician and two nurses were repeatedly unable to make any of the proposed appointments, and were finally considered refusals. Table 1 presents the demographic characteristics of the participating staff members.

Table 1. Demographic characteristics of the respondents

	Physicians (N=19)	Nurses (N=17)
Age :		
<30 years	1	7
31-40 years	10	8
>40 years	8	2
Sex :		
Male	9	1
Female	10	16
Have children	10	4
Professional experience >10 years	8	2

In this paper we present the results on reported NICU practices: the decision-making process and the role of parents in ethical dilemmas, how and when treatment is withdrawn, and the law as it is and as the respondents think it should be. We then describe what seems to have changed since the first study and some factors involved in these changes.

Results

Treatment withdrawal in the NICU.

All caregivers responded affirmatively to the question "After NICU admission, is it possible to decide to withdraw treatment ?" The most often quoted basis for the decision was the patient's future quality of life, when, for example the *"child would be bedridden, with no relational life, without any*

communication." It was also unanimously agreed that these decisions are made in staff meetings so that everyone can *"have the opportunity to express one's beliefs"* and *"listen to others' views, including doctors from other specialties"*. A consensus is required.

Parental involvement in decision-making

Physicians and nurses in the three centres answered very similarly: when a decision to limit treatment is envisioned, the team explores the parents' views, and if these differ from the staff plans, an attempt is made to convince the parents. *"The goal is to make the parents assent to our decision, not the contrary."* However, physicians in centre C emphasised the importance of dialogue with parents. Individual parents may differ greatly : some prefer minimal involvement in decisions, while others assert their rights to participate in discussions and decisions. It is essential to take time to talk with them, case by case, in an atmosphere of confidence: *"We need to get tacit agreement from the parents"*. They consider that is difficult to describe such *"a subjective, individualised dialogue"*. Parents' opinions on treatment withdrawal are explored indirectly. *"The main difficulty is getting their opinion indirectly ... and we have failed when they say, 'oh, you want us to tell you to pull the plug?'"* The waiting time may be difficult for nurses as it forces them to confront the parents' distress and the child's suffering. *"We tend to say that we wait too much! Every day, we're in the room with the child and the parents, it is harder for us than for doctors, who just drop by"*. Also in C, a few nurses described the concern sometimes expressed by parents: *"They are afraid of being asked for permission to kill their child"*. These nurses appeared to identify with parents: *"As a parent I would rather be told my baby's heart stopped and not have it on my conscience. It's hard enough to lose a child."*

In all three centres, regardless of the practices, the spontaneous comments of doctors and nurses stressed their desire to spare the parents the responsibility for the decision. They worried that direct parental involvement in the decision to withdraw treatment might induce huge guilt. *"They should not feel that they participated in the decision to end their baby's life; it is very guilt-inducing and prevents grieving."* Most professionals in the three centres spontaneously added that it is their responsibility to reject unreasonable obstinacy in pursuing futile intensive care. In case of persistent disagreement with

parents opposing treatment withdrawal, a few doctors also explained: *"we might hide the truth and tell parents that we have reached the limits of treatments; we say that the baby's condition is critical"*.

Procedure to withdraw life-sustaining treatment

All caregivers in the three centers provided similar answers to the question: "What is the procedure for the withdrawal of treatment?" Preserving the *"child's comfort and dignity"* was always a priority. However, the details of the medical procedure differed greatly from one doctor and from one centre to another. *"We each act on our own responsibility, as doctors. It's a grey area. We don't talk much between us, there are perhaps feelings of guilt or shame."* Doctors very rarely mentioned the administration of drugs with the purpose of ending a patient's life: *"It exists, but I don't do it. In principle it should not be done here."* When intensive treatment is withdrawn, most respondents explained: *"We administer sedatives and then remove what needs to be removed, preferably in the presence of parents."*

The rituals desired by the parents are explored and taken into account. *"They are asked if they want to be present, to have a baptism, a ceremony, the presence of the family, photos, mementos...."* The process is gradual and may sometimes take several days. Caregivers emphasised the importance of the parents' presence when their child dies to avoid *"a feeling that they abandoned the baby, which could complicate their mourning"*. The presence of parents was also described as beneficial for caregivers: *"It soothes us if they are there."*

Knowledge about French law on end-of-life situations

Four doctors and three nurses could not answer the question "What does French law say about end-of-life situations?" The others answered that the law *"prohibits active euthanasia but authorises passive euthanasia"*. Only one senior doctor pointed out that *"active euthanasia is replaced by the interruption of intensive treatment with palliative care and relief of the suffering that accompanies the end of life."*

Physicians more often than nurses mentioned the 2005 Leonetti law. A few doctors criticised it. They considered it *"hypocritical, since euthanasia is prohibited, but sedatives in large doses cause death."* They explained that treatment withdrawal *"is less active but ... the same, it is a different representation of the same thing."* In contrast, older doctors appeared to value the clarification brought about by the new law: "

Active euthanasia has been replaced by treatment withdrawal. The law will allow young doctors to agree with the terms of the law".

Opinions about the current law

Almost all the respondents understood the question about whether the law should be changed as asking whether euthanasia should be legalised. Most answered in the negative, giving several reasons: *"Morally the taboo against killing is fundamental."* The collegial procedure *"on a case by case basis, doing what is best for each patient, avoids abuses."* Finally, most respondents considered that *"the law cannot deal with this: it would be a headache from a medical and a human point of view."*

A few doctors added that the risks of litigation were small: *"the judges know exactly what is happening, and parents do not take us to court."* Senior doctors further explained that *"now there is a law and in most cases you can stay within it. Before, we had no law, now it's done."*

The few caregivers who expressed a wish *"for the legalization of euthanasia"* felt that it would protect them against litigation and that it could, especially in cases of unreasonable obstinacy by the family, ease the decision process.

Changes over the last 10 years

Changes were assessed in three ways. First, we asked the eight physicians with at least 10 years of experience (three of whom had participated in the first survey) if they thought practices had changed over the past 10 years. According to these doctors, the biggest change concerned transparency for parents. *"There are fewer lies, more honesty."* *"We listen more to parents."* Other changes concerned the increasing rarity of the use of drugs for actively ending life, and the increasing presence of parents and rituals during the dying process: *"Before, we injected potassium chloride and told the parents that their child's heart stopped during the night."*

Secondly, we compared the results with the EURONIC interviews. The analysis confirmed a greater attention to the dialogue with parents, fewer lies about the end of life procedure, the increasingly rare use of drugs for actively ending life, the more gradual nature of the process leading to death of the child, and the emphasis on the presence of parents.

Some spontaneous comments also hinted at some changes. All the most senior doctors expressed their relief. *"Ending life was no longer possible for me,"* said one. Another confided: *"I have fewer nightmares. There is more satisfaction in work well done"*. Another added that the purpose changed: *"When we stop intensive care, our intention is no longer to end life but to provide palliative care and control pain, even at the risk of hastening death."*

In contrast, younger physicians with less experience appeared more ambivalent, particularly as regards parental involvement. They felt that their task is more complicated today: *"There were not only disadvantages before, making decisions without parents. Involving parents is more demanding, more emotional. It is more trouble to everyone. But it is a sacrifice that is needed from an ethical point of view."*

Differences by respondent age and professional role

Differences between nurses and physicians remained evident in their responses. Nurses felt more emotionally involved, sometimes identified with parents and became attached to them and to the baby. The effect of age showed with older physicians reporting a better knowledge of the law and a more positive view of its contents. Their younger colleagues were more often critical of the new legislation and reported difficulties in discussions with parents about stopping treatment.

The effect of parenthood on discourse and practices could not be identified, especially given that it is also related to other factors, such as age and occupational status.

Discussion

Ten years after the EURONIC studies and the publication of new French laws and recommendations, physicians and nurses reported more dialogue with parents in the decision-making process and more transparency about the end-of-life procedure; active termination of life was extremely rare; and respectful support was provided to dying newborns and their families. The collegial decision-making process, the possibility of treatment withdrawal, and the administration of sedatives or analgesics to control pain even though they may hasten death, the need to spare parents the burden of responsibility

22/03/11

for the decision and the partial ignorance of the law were very similar to the results reported, about 10 years ago, by the EURONIC study.

For comparison's sake, we used the same method as in the EURONIC qualitative study.[3] In depth interviews allowed us to examine feelings, attitudes and complex behaviours, exploring both the declared and the implicit rules used by health care professionals. Our results, however, are based on self-reported not on actual practices. Only a prospective observational study would have allowed a description of actual practices.[11]

Our results are in keeping with the current opinions among French neonatologists. In the first qualitative study we found that the types of ethical dilemmas described and their management were fairly homogeneous in the two participating centres and that qualitative results agreed overall with those reported by the quantitative survey in France, as well as with guidelines published by the French federation of neonatologists. In this new study, there were again more similarities than differences between the participating centres, and the responses were again consistent with recent publications and guidelines.[1,12-13] This observation should be confirmed in a larger study.

The French attitude aims at sparing parents the burden of responsibility, thought to be a source of guilt or remorse. We examined whether any evidence supports this concern about the long-term consequences to the emotional health of parents who are involved in end-of-life decisions for their newborn. A recent study compared the Canadian medical environment, thought to favor parental autonomy, with the more paternalistic environment in France. The study found no association between the parents' guilt feelings and their degree of involvement in the decision.[14] In contrast, an American publication suggested that "families may not want the authority that prevailing bioethics doctrine insists belong to them." [15] Another pointed out that parents wished to play an active role in decision-making for their infant but did not seek sole decision making capacity.[16]

Our results about the possibility of treatment withdrawal were similar to those in the first study. Now, however, caregivers favoured towards the presence of parents during the dying process. This attitude differs from that observed 10 years ago and probably results from the new legislation on patients' end-of-life rights. It also reflects a general trend in practices surrounding perinatal grief, in which the presence of the family, rituals and ceremony are now recommended.[17]

Most of the health-care professionals in our study did not challenge the prohibition of euthanasia, and a much smaller minority than 10 years ago reported acts of active termination of life. A significant number, however, said that they were ignorant of the law and did not know what it said. This finding was identical to that of the first study. This might appear surprising given that the French laws are new and received substantial publicity. It is unclear whether this was a genuine ignorance or a disguised refusal to discuss sensitive issues. The older doctors appeared to be better informed and more supportive of the new laws, perhaps because of their struggles with the ethical dilemmas of an earlier time and their experience and training in medical ethics across a career of articles, discussions, and professional committees.[12,13] The younger doctors did not challenge the ethical principles that underlie the new laws. On the other hand, they sometimes considered that the application of these new laws makes their job more complex and more emotionally draining than when parents were kept in the background. It is likely that providing support to parents throughout the decision-making process and having to face their distress directly and repeatedly requires experience and training that younger doctors have not yet acquired.

Conclusion

During the past few years, neonatal caregivers have paid increasing attention to parents' views and now discuss with them the clinical decisions to be made for their newborns. The medical and legal regulation of practices have allowed better support and more humane care for babies and their parents during withdrawal of treatment. These new ethical guidelines and legal requirements have clarified the issues, and now allow caregivers to obey the law far more than in the past.

Other studies comparing different medical environments and degrees of parental involvement in the decision would help to assess the consequences on parents' long term emotional well-being of practices related to decision-making and the dying process. A comparative survey should also be conducted at a European level to look at possible changes in practices and attitudes based on legislative changes and guidelines and to assess the persistence of some of the unique features related to active termination of life and parental involvement in decision-making that EURONIC highlighted in countries such as the Netherlands or France.

22/03/11

Acknowledgements

We wish to thank the departments that participated in the study and all the respondents who gave us their time and answered our questions. We are grateful to Sylvie Seguret for her helpful comments about early version of this manuscript.

References

1. Cuttini M, Casotto V, de Vonderweid U et al. Neonatal end-of-life decisions and bioethical perspectives. *Early Hum Dev* 2009; 85:S21-25.
2. De Leeuw R, Cuttini M, Nadai M et al. Treatment choices for extremely preterm infants: an international perspective. *J Pediatr* 2000; 137: 608-616.
3. Garel M, Gosme-Seguret S, Kaminski M et al. Les prises de décisions éthiques en réanimation néonatale. Enquête auprès des soignants de deux centres français. *Arch Pédiatr* 1997, 4, 662-670.
4. Cuttini M, Nadai M, Kaminski M et al. End-of-life decisions in neonatal intensive care: physicians' self-reported practices in seven European countries. *Lancet* 2000; 355:2112-18
5. Rebagliato M, Cuttini M, Broggin L et al. Physicians' attitudes and relationship with self-reported practices in 10 European countries. *JAMA* 2000; 284: 2451-2459.
6. McHaffie HE, Cuttini M, Brolz-Voit G et al. Withholding/withdrawing treatment from neonates : legislation and officila gudelines across Europe. *J Med Ethics* 1999; 25: 440-6.
7. Verhagen E, Sauer PJ. The Groningen protocol-euthanasia in severely ill newborns. *N Engl J Med* 2005; 352: 959-62.
8. Verhagen E. End of life decisions in newborns in the Netherlands: medical and legal aspects of the Groningen protocol. *Med Law* 2006; 25: 399-407.
9. Verloove-Vanhorick SP. Management of the neonate at the limits of viability : the Dutch viewpoint. *BJOG* 2006; 113 (supl 3): 13-6.
10. Malterud K. Qualitative research: standards, challenges, and guidelines. *Lancet* 2001;358:483-88.
11. Orfali K. parental role in medical decision-making : fact or fiction ?A comparative study of ethical dilemmas in French and American neonatal intensive care units. *Soc Sc Med* 2004; 58: 2009-2022.
12. Dageville C, Rameix S, Andrini P et al. Groupe de réflexion sur les aspects éthiques de la périnatalogie. Fin de vie en médecine néonatale à la lumière de la loi. *Arch Pédiatr* 2007; 14:1219-1230.
13. Azria E, Bétremieux P, Caeymaex L et al. Groupe de réflexion sur les aspects éthiques de la périnatalogie. L'information dans le contexte du soin périnatal : aspects éthiques. *Arch Pediatr* 2007; 14:1231-1239.
14. Carnevale F A, Canoui P, Cremer R et al. Parental involvement in treatment decisions regarding their critically ill child : A comparative study of France and Quebec. *Pediatr Crit Care Med* 2007; 8: 337-342.

15. Paris JJ, Graham N, Shreiber MD et al. Approaches to end-of-life decision-making in the NICU : insights from Dostoevsky's The Grand Inquisitor. *Journal of Perinatology* 2006; 26: 389-391.
16. Partridge JC, Martinez AM, Nishida H et al. International comparison of care for very low birth weight infants: parents' perceptions of counseling and decision-making. *Pediatrics* 2005; 116: 263-271.
17. Murray JA, Terry DJ, Vance JC et al. Effects of a program of intervention on parental distress following infant death. *Death Studies* 2000; 24: 275-305.