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JP Quenot[1], JP Rigaud[2], Prin[1], S. Barbar[1], A. Pavon[1], M. Hamet[1], N. Jacquiot[1], B. Blettery[1], C. Hervé[3], PE. Charles[1], G. Moutel[3]

[1] Service de Réanimation Médicale, CHU Dijon

[2] Service de Réanimation Polyvalente, CH Dieppe

Laboratoire d'éthique médicale, faculté de médecine Paris V

Abstract

Background: Since the 2005 French law on end of life and patients' rights, it is unclear whether practices have evolved. We investigated whether an intensive communication strategy based on this law would influence practices in terms of withholding and withdrawing treatment (WWT), and outcome of patients hospitalised in intensive care (ICU).

Methods: Single-centre two-period study, before and after the law. Between periods, an intensive strategy for communication was developed and implemented, comprising regular meetings and modalities for WWT. We examined medical records of all patients who died in the ICU or in-hospital during both periods.

Results: In total, out of 2478 patients admitted in period 1, 678(31%) died in ICU and 823/2940 (28%) in period 2. In period 1, among patients who died in ICU, 45% died further to a decision to WWT vs 85% in period 2 ($p<0.01$). Among these, median time delay between ICU admission and initiation of decision-making process was significantly different (6-7 days in period 1 vs 3-5 days in period 2, $p<0.05$). Similarly, median time from admission to actual WWT decision was significantly shorter in period 2 (11-13 days in period 1 vs 4-6 days in period 2, $p<0.05$). Finally, median time from admission to death in ICU further to a decision to WWT was 13-15 days in period 1 vs 7-8 days in period 2, $p<0.05$. Reasons for WWT were not significantly different between periods.

Conclusion: Intensive communication brings about quicker end-of-life decision-making in the ICU. The new law has the advantage of providing a legal framework.

Introduction

Since the advent of the discipline of critical care almost half a century ago, it has become clear that in some patients, there are limits to the therapeutic engagement. The use of all available resources to maintain artificial life support can sometimes border on the excessive, not to say unreasonable, given the hopeless prognosis and low quality of life expected for the patient, or the excessive economic cost [1-3].

Early studies exploring this concept led to the proposal of a scale of therapeutic engagement [4]. Further reports evaluating practices in terms of withholding and withdrawing treatment in critical care in France [1, 5] brought the medical community to a collective realisation that the conceptual framework needed to be reviewed. This ushered in an era of profound reflection on the role of the patient, their proxies, and the responsibility of physicians and paramedical staff in end-of-life decision-making. The results of this reflection have materialised in different forms in different countries, depending on the local legal and cultural context [6-11].

In France, this process of reflection led to new legislation, dating from 22 April 2005, relative to patient rights at the end-of-life, the so-called “Leonetti” law [12-13]. Briefly, this law gives new rights to patients and clarifies medical practices regarding end-of-life care.

We performed a before-and-after, interventional study to investigate whether an intensive communication strategy regarding end-of-life decisions, taking into account the dispositions of the law dated 22 April 2005, would have an influence on practices in terms of withholding and withdrawing treatment, and on the outcome of patients hospitalised in critical care.

Methods

This single-centre study was performed over two periods, namely before the law of 22 April 2005, from January 2000-March 2005 (period 1), and after the law, from January 2006 to December 2009 (period 2). The institutional review board (Comité de Protection des Personnes, Dijon) approved the protocol.

Between the 2 phases, our healthcare team (physicians, nurses, nurses' aids, psychologist) developed an intensive strategy for communication on the level of therapeutic engagement for every patient in the intensive care unit (ICU) according to clinical severity and expected prognosis. The communication strategy and related structural organisation within the department is described in Table 1.

Data Collection

We examined the medical records of all patients who died in the ICU or in-hospital after discharge to another department, during the two study periods.

We recorded for all patients: age, sex, simplified acute physiological score (SAPS II) (17), comorbidities and diagnosis at admission as defined by the International Classification of Disease, 9th Ed, clinical Modification (ICD-9-CM); Knaus score (18), type of admission (medical or surgical), the person who initiated the decision-making process on withholding of withdrawal of treatment for each patient; reasons for withholding or withdrawing treatment (choice of prespecified items); whether an external expert was consulted (clinician specialist of the main disease presented by the patient); existence of any information concerning withholding or withdrawal of treatment emanating from the patient or their proxies; whether any end-of-life decisions were noted in the medical file; frequency of use of morphine and/or midazolam; whether the patient died in the ICU or in-hospital.

Withholding was defined as a planned decision not to initiate treatment that was otherwise indicated. Withdrawal was defined as interruption of ongoing treatments. Withholding or withdrawal of treatment included the possibility that a patient could be transferred to another hospital Department with instructions not be to readmitted to the ICU.

For all patients who had died in the ICU or in-hospital further to discharge from the ICU to another department in period 1, we examined the medical records to identify whether death was due to limitation or withdrawal of ongoing treatment; and in cases where a decision to withhold or withdraw treatment had been made, what had been the reasons for this decision.

Overall, 99% of all deaths from both periods were analysed.

Data relating to advance directives were noted as « not applicable » in period 1, since they pre-dated the 2005 legislation. Similarly, the first data on officially appointed proxies appeared in 2002, when a specific law allowing for the appointment of surrogates was introduced and put in practice in all hospitals nationwide.

It should be noted that the ICU comprised 8 beds in period 1, and 15 in period 2, with an intermediate transitional period with an incremental increase of capacity to 11 then 13 beds.

Statistical Analysis

Quantitative variables are presented as median [Interquartile range] and qualitative variables as number (percentage). Quantitative variables were compared using the Wilcoxon test and qualitative data with the Chi square test or Fisher's exact test. All tests were two-tailed and a p-value <0.05 was considered statistically significant. Bonferroni correction for multiple comparisons was applied where appropriate. All analyses were performed using SAS version 9.1 (SAS Institute, Cary, NC, USA).

Results

In total, 2478 patients were admitted in period 1, of whom 520 (21%) died in critical care, and 158 (10%) in-hospital after discharge from critical care. In period 2, 2940 patients were admitted, of whom 672 (23%) died in critical care, and 151 (5%) in-hospital.

The baseline characteristics of all patients who died in critical care or in-hospital after discharge to another department are displayed in Table 2.

Median age [IQR] was 65 [53-78] in period 1 and 66 [54-78] in period 2. Median [IQR] SAPS II scores were respectively 65 [57-72] and 63 [54-75] in periods 1 and 2. Most admissions were for medical pathologies (93% in period 1, 92% in period 2). Previous state of health as evaluated by the Knaus score did not differ significantly between periods. Similarly, no significant difference between periods was observed in admission diagnosis or comorbidities.

In period 1, a written notification of a decision to withhold or withdraw treatment was found in the medical files of 306 (45%) patients who died , versus 700 (85%) in period 2 ($p<0.01$). The difference was statistically significant for withholding alone, withdrawal alone, and for withholding plus withdrawal (table 1).

In the majority of cases, the decision with withhold or withdraw therapy was made in the critical care department (95% in period 1 vs 93% in period 2).

For the subsequent analyses, we considered only the 306 patients in period 1 and the 700 patients in period 2 who died further to a decision to withhold or withdraw treatment.

Time between admission to ICU and initiation of end-of-life decision-making process (Table 3)

The median time delay (in days) between admission to the ICU and the initiation of a decision-making process regarding possible withholding or withdrawal of therapy was significantly different between periods (Table 3). Similarly, the median time delay from admission to the actual decision to withhold or withdraw therapy was significantly shorter in

period 2 (Table 3). We also observed a statistically significant difference between periods in median time delays [IQR] (in days) from admission to death in ICU and in-hospital, further to a decision to withhold treatment, withdraw treatment, or both.

Reasons for Withholding or Withdrawing Treatment in both periods (Table 4)

The reasons leading to a decision to withhold or withdraw treatment were documented in 68% of medical files in period 1 vs 99% in period 2 ($p<0.01$). There was no significant change in the main reasons cited in both periods, with the exception of expected future quality of life for the patient, which was cited significantly more frequently in period 2 as a reason for withholding or withdrawing therapy (See Electronic Supplementary Material). Similarly, there was also a significant difference between periods in the citation rate of non-response to optimal therapy (Table 4).

Persons who initiated the decision-making process (Table 5)

The person(s) who initiated the decision-making process regarding the need to withhold or withdraw therapy (expressed as percent of patients) differed significantly between periods. In period 2, the process was more often initiated by close family members and non-physician staff members (nurses, nurses' aids) and this information was significantly less frequently unknown. Only four patients had prepared advance directives (all in period 2).

Use of morphine and midazolam during withholding or withdrawal of treatment (Table 6)

The pharmacological environment used for pain and anxiety relief in patients in whom a decision to withhold or withdraw treatment had been made showed significantly more frequent use of morphine and midazolam during period 2 as compared to period 1 (Table 6).

The information regarding any decision to withhold or withdraw treatment was given to the patient in 5% of cases in period 1, vs 9% in period 2 (p=NS). The same information was given to the families in 65% of patients in period 1 vs 95% in period 2 ($p<0.01$).

An external expert (clinician from another discipline) was consulted in an advisory capacity for 45% of decisions to withhold or withdraw therapy in period 1 vs 65% in period 2 ($p<0.01$). Experts were mainly consulted by telephone in both periods (85% in period 1 vs 87% in period 2, p=NS).

Discussion

Our study shows that the number of deaths occurring further to a decision to withhold or withdraw therapy in patients hospitalised in the ICU differed significantly between the period before the new French law on patients' rights at the end-of-life (45%), and the period after the new legislation (85%), when an intensive communication strategy around the dispositions of this law had been put in place. This study mainly relates to the process of reflection and introspection concerning the ethics of end-of-life care, and how this process can and should become more consensual. The results of our intensive communication strategy have been to bring about a collective raising of awareness within the ICU. Official guidelines from national societies published in 2000 had previously made a start at laying down a framework for this difficult domain [14]. There was a clear need to allay the fears of caregivers who, although not trained in end-of-life care, were almost "obliged" to make difficult end-of-life decisions on a routine basis. Similarly, there was a need to communicate, in a clear and transparent manner, on the ethics of end-of-life decisions, and to allow all those involved in end-of-life care to have access to the medical and ethical knowledge that could help them to make and follow through on their decisions.

Previous studies have reported death rates of 50% to 78% after WWT decisions [1, 15]. These studies were performed before the 2005 law and indeed, our results from period 1 are in line with these results, with 45% of deaths occurring further to a decision to forego therapy.

The second period of our study, after the new French legislation of 2005, saw the rate of deaths after limiting of life-sustaining therapy increase to 85% in our department, which is coherent with the rates reported in other studies conducted after 2005 [2, 16-18]. It should be noted that studies conducted in different religious or geographic contexts, particularly within Europe, can give differing results.

This could reflect not a true evolution in practices, but rather a better communication regarding what really happens, facilitated by the law of 2005, which rendered it easier to

make such decisions and note them in the patient's file. By creating a legal framework for end-of-life decisions, the new law has helped to exculpate physicians who previously laboured in a no-man's-land of uncertainty about the ethics of end-of-life practices.

Our results further underline the importance of a clear decision-making procedure within an ICU that includes good communication and regular collegial meetings to facilitate discussion. The new strategy we introduced comprising open communication and daily meetings with all staff members made it possible for all relevant parties to advance their opinions and reach – within a shorter time frame – a consensual decision about WWT options. Again, before the law of 22 April 2005, physicians in France had great difficulty in making decisions pertaining to suspension of life-sustaining therapies, and it was especially problematic to document such a decision in the medical file. With the legal framework created by the new law, the decision-making process has been greatly facilitated, and has been greeted with widespread relief among the medical profession. In the study by Ferrand et al [1], among the patients in whom a decision to forego life-sustaining therapy was made, this decision was generally made within 2 days (in 40.5%), and within 30 days of admission to the ICU for 50%. In our study, the decision-making process was initiated after a median of 6-7 days in period 1, and 3-5 days in period 2, leading to a decision being made within a median of 11-13 days vs 4-6 days in period 1 vs 2 respectively. This clearly underlines that the greater communication facilitated the initiation of the decision-making process, even though the consequence was a significant reduction in the time delay to death.

The main motives cited as justification for deciding to withhold or withdraw therapy did not change significantly after the new legislation, except for quality of life and non-response to maximal medical therapy, which were more frequently cited in the later period. (See Electronic Supplementary Material). The new law specifically mentions that excessively burdensome treatment should be avoided and future quality of life taken into consideration, whereby the likelihood of a very low future quality of life would be considered suitable

justification for WWT. Thus, these factors are legitimised by the law as reasons for foregoing life-sustaining therapy. In the literature, other reported reasons for suspending life-sustaining therapy include physical or psychological suffering, or economic reasons [1, 18]. However, cost was not a factor in our study, since in the French medical health system, neither the patients nor the doctors are directly concerned by the cost of care.

eWe noted an increase in the proportion of end-of-life decisions initiated by the patient's close family or the non-physician personnel (nurses, nurses' aids). Several studies assessing the collegial nature of decisions to forego life-sustaining therapy mention the lack of communication and interaction between the caregivers and the patients' close family members when discussing the patient's future [19-21]. Indeed, Stricker et al highlighted the need for improved emotional support, coordination of care and communication in their study of family satisfaction among the relatives of 996 Swiss ICU patients [16, 22]. Therefore, it is of particular importance to have an intensive communication strategy involving all staff members as well as the patient's family and/or appointed surrogates. Contrary to reports that nurses are not sufficiently involved in end-of-life decisions [1, 15, 23-34], we observed in our study that the intensive communication helped to increase the participation of nursing staff. Indeed, Ferrand et al previously reported that nurses often cited emotional distress as a source of dissatisfaction [35], whereas in our study, the greater implication of nurses in the end-of-life decision-making process may have helped them to avoid this moral distress through greater communication.

The intensive communication strategy introduced in our department made it possible to identify at an earlier stage patients who were likely to later have withholding or withdrawal of treatment. In view of the fact that there is a now a legal basis for such decisions, perhaps it has simply become easier to reach such decisions. Despite the improvements achieved with an intensive communication strategy in our department after the new French legislation on end-of-life patient rights, there are undoubtedly several areas where there is still room for further progress. Many patients do not have officially appointed surrogates or proxies, and

the level of communication regarding this possibility could likely be improved. Secondly, external consultants are often just consulted by telephone. More active involvement in grand rounds or interprofessional meetings could help to yield a more positive contribution from outside experts. Third, while the new law lays down good principles for end-of-life care, these dispositions are of little use and impossible to put into application if the whole medical and non-physician staff is not sufficiently aware and involved. Thus, regular training and constant communication are necessary, as well as psychological support. End-of-life care should be seen as extending beyond the patient to include the patient's family, and is not simply a question of treating a specific disease.

Limitations

This was a single-centre study, including mainly medical patients (90%). Thus, our results may not be extrapolated to all ICU populations, or multiple centres, as it would be difficult to obtain uniform practices. Secondly, data from period 1 were retrospective, and there were probably missing data or insufficiently exploited files. Thirdly, decisions to withhold or withdraw treatment were not generally made during the night or during the weekend, because of the absence of sufficient staff to guarantee the collegial decision-making procedures. e Fourthly, the person who initiated the decision-making process regarding end-of-life options can be difficult to identify, particularly in period 1, where notations in the medical file were less frequent and less detailed. e Fifth, our strategy of intensive communication was developed as a policy in the department and is not necessarily replicable in other departments. In addition, it is not possible to conclude that the changes observed in our practices were due solely to the introduction of the new legislation. e Sixth, since the ICU capacity increased between periods, there is a possibility that the patient profile changed between periods. Lastly, while doctors in France are not directly concerned by the cost of care, we cannot exclude that economical considerations due to limited resources may have influenced their decisions to withhold or withdraw therapy.

Conclusions

The new law of 2005 in France on patient rights at end-of-life has made it possible to introduce an active communication strategy regarding end-of-life decisions, with a true legal framework, probably limiting excessively burdensome treatment.

Intensive communication makes it possible to identify earlier patients who are likely to evolve towards WWT, which brings about quicker decision-making regarding end-of-life in the ICU.

We noted greater involvement of close family and nursing staff in initiating decisions relating to end-of-life. The new law has the advantage of providing a legal framework to free physicians of the burden of unguided decision-making in this difficult context.

Table 1: Description of the elements comprising the intensive communication strategy regarding end-of-life decisions implemented in the intensive care unit according to the French law of 22 April 2005

Organisation:

- Introduce unrestricted visiting hours
- Increase availability of the caregiving team to discuss clinical evolution and therapeutic engagement
- Assign a meeting room specifically reserved for meetings with patients' families
- Define fixed appointments with families for meetings, without interruptions (physicians' telephones switched off)
- Apprise entire caregiving team of new communication strategy (defined below)
- Implement continuing medical education training in end-of-life ethics before introduction of new communication strategy

Communication:

- Daily meetings of the caregiving team and with the patient and/or their family to :
    - decide on the level of therapeutic engagement (according to diagnosis, prognosis, comorbidities, previous quality of life, life expectancy, patient's wishes as expressed either directly or indirectly through advance directives)
    - define modalities for withholding or withdrawing treatment, in accordance with the 2005 law, and initiate collegial procedure in concert with an outside expert
    - discuss options for use of pain and anxiety relieving medications.
- Create a special "Ethics" section in every patient's medical record, accessible to all

members of the caregiving team, to document all discussions and decisions relating to the level of therapeutic engagement

- Organise debriefing for members of caregiving team to discuss emotionally stressful cases

Table 2: Main characteristics of patients who died in ICU or in-hospital during the two study periods

Variable	**Period 1** (n=678)	**Period 2** (n=823)
Age, years, median [IQR]	65 [53-78]	66 [54-78]
Male sex, *no. (%)*	420 (62)	485 (59)
Coexisting conditions, *no. (%)*		
Immunodepression	74 (8)	81 (10)
Of which cancer	61/74 (82)	67/81 (83)
Chronic obstructive pulmonary disease	101 (15)	115 (14)
Chronic heart failure	61 (9)	66 (8)
Chronic renal failure	47 (7)	57 (7)
Cirrhosis	41 (6)	66 (8)
Diabetes Mellitus	95 (14)	107 (13)
Knaus, *n. (%)*		
I	74 (11)	99 (12)
II	359 (53)	461 (56)
III	189 (28)	197 (24)
IV	498 (8)	66 (8)

SAPS II, median [IQR]	65 [57-72]	63 [54-75]
Category of admission, *no. (%)*		
Medical	630 (93)	758 (92)
Scheduled surgery	28 (4)	41 (5)
Emergency surgery	20 (3)	24 (3)
Reason for ICU admission, *no. (%)*		
Acute respiratory failure	387 (57)	478 (58)
Shock	149 (22)	198 (24)
Coma	61 (9)	58 (7)
Post-operative	48 (7)	65 (8)
Acute renal failure	20 (3)	8 (1)
Other	13 (2)	16 (2)
Withholding only, *no. (%)*[#]	68 (10)	165 (20)
Withdrawal only, *no (%)*[#]	102 (15)	288 (35)
Both Withholding and withdrawal, *no (%)*[#]	136 (20)	247 (30)
% Decisions to withhold or withdraw made in ICU	95	93

[#]$p<0.05$ for comparison between periods; all other patients died with full support.

IQR, Interquartile range.

Table 3. Time delay between admission and initiation of end-of-life decision-making process, actual decision to withhold or withdraw therapy, and death in ICU or in-hospital in the two study periods.

	Period 1 **N=306**			**Period 2** **N=700**		
Time delay, *days*	Withholding only N=68	Withdrawal only N=102	Withholding and Withdrawal N=136	Withholding only N=165	Withdrawal only N=288	Withholding and Withdrawal N=247
Initiation of decision-making process[#], Median, [IQR]	6 [3-9]	7 [3-10]	7 [4-10]	3 [2-6]	5 [2-7]	5 [2-7]
Decision[#], Median [IQR]	11 [7-15]	13 [7-18]	11 [8-16]	4 [2-7]	6 [3-8]	6 [3-8]
Death in ICU[#], Median [IQR]	15 [11-21]	14 [9-17]	13 [10-19]	8 [6-13]	7 [4-9]	7 [4-9]

Death in-hospital[#], Median [IQR]	25 [14-31]	15 [12-17]	14 [11-22]	11 [9-16]	8 [6-11]	10 [7-15]

[#]p<0.05 between periods for each category

Table 4 : Reasons cited to justify a decision to withhold or withdraw therapy in periods 1 and 2.

	Period 1 N=306			**Period 2 N=700**		
Reason	Withholding only N=68	Withdrawal only N=102	Withholding and Withdrawal N=136	Withholding only N=165	Withdrawal only N=288	Withholding and Withdrawal N=247
Age	22 (32%)	36 (35%)	45 (33%)	56 (34%)	106 (37%)	94 (38%)
Previous autonomy	18 (27%)	21 (21%)	26 (19%)	31 (19%)	69 (24%)	44 (18%)
Comorbidities	26 (39%)	42 (41)	39 (29%)	56 (34%)	103 (36%)	86 (35)
Expected future quality of life	37 (54%)	48 (47%)	53 (39%)	79 (48%)	146 (51%)	132 (46%)
Diagnosis at admission	8 (12%)	9 (9%)	20 (15%)	23 (14%)	32 (11%)	42 (17%)

Non-response to maximal therapy	37 (55%)	49 (48%)	18 (43%)	74 (45%)	147 (51%)	113 (46%)
Multi-organ failure	14 (21%)	19 (19%)	20 (15%)	26 (16%)	49 (17%)	32 (13%)

Totals exceed 100% as more than one reason could be cited for each decision to withhold or withdraw therapy.

Table 5 : Person who initiated the decision-making process in both periods

	Period 1 **N=306**			**Period 2** **N=700**		
Person	Withholding only N=68	Withdrawal only N=102	Withholding and Withdrawal N=136	Withholding only N=165	Withdrawal only N=288	Withholding and Withdrawal N=247
Patient						
Competent to make decision	2 (3%)	3 (3%)	6 (4%)	8 (5%)	8 (3%)	12 (5%)
By advance directives	N/A	N/A	N/A	1 (0.5%)	1 (0.3%)	2 (0.8%)
Close family members*	5 (8%)	7 (7%)	9 (7%)	30 (18%)	60 (21%)	47 (19%)

Appointed surrogate	7 (10%)	6 (6%)	6 (4%)	20 (12%)	32 (11%)	22 (9%)
Non-physician caregiver (nurse, nurse's aid)*	5 (8%)	4 (4%)	14 (10%)	55 (33%)	83 (29%)	96 (39%)
Medical staff (physician)	46 (68%)	66 (65%)	94 (69%)	119 (71%)	210 (73%)	170 (69%)
Unknown*	16 (23%)	18 (18%)	26 (19%)	3 (2%)	1 (0.3%)	1 (0.4%)

Totals exceed 100% as more than one person could initiate each decision to withhold or withdraw therapy simultaneously.

*$p<0.05$ for comparison period 1 vs period 2 for each category

Table 6 : Use of morphine and midazolam during withholding or withdrawal of therapy in both periods.

	Period 1 N=306			**Period 2 N=700**		
Pain and Anxiety Relieving Medication	Withholding only N=68	Withdrawal only N=102	Withholding and Withdrawal N=136	Withholding only N=165	Withdrawal only N=288	Withholding and Withdrawal N=247
Morphine*	2 (3%)	10 (10%)	20 (15%)	20 (12%)	167 (58%)	163 (66%)
Midazolam*	2 (3%)	8 (8%)	17 (13%)	15 (9%)	129 (45%)	133 (54%)

Totals exceed 100% as both drugs could be used in the same patient.

*p<0.05 for comparison period 1 vs period 2 for the three categories

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