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Withholding or withdrawing life-sustaining treatments in the COVID-19 pandemic: adherence to legal standards

Virginie Guastella ¹, Céline Lambert,² Aurore Lafforgue,¹ Pauline Metretin,¹ Aude Verstrete,³ Sophie Watelet,³ Élise Perceau-Chambard,⁴ Alexandre Lautrette⁵

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¹Palliative Care Departement, Centre Hospitalier Universitaire de Clermont-Ferrand, Clermont-Ferrand, France

²DRCI, CHU Clermont-Ferrand, Clermont-Ferrand, France

³Hospices Civils de Lyon, Lyon, France

⁴Palliative Care Departement, Hospices Civils de Lyon, Lyon, France

⁵ICU, Centre Jean Perrin, Clermont-Ferrand, France

Correspondence to

Dr Virginie Guastella, Centre Hospitalier Universitaire de Clermont-Ferrand, Clermont-Ferrand 63000, France; vguastella@chu-clermontferrand.fr

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ABSTRACT

Objectives In France, when the patient is unable to express his wishes, the decision to withhold or withdraw life-sustaining treatment (WWLST) is made following a collegial procedure described by a law. The aim of our study was to assess how closely this WWLST decision-making procedure in end of life patients was maintained during the COVID-19 pandemic.

Methods This retrospective observational multicentre study compared the rate of non-compliance with WWLST decision-making procedures during the pandemic period from March to June 2020 with control period in 2019, in Clermont-Ferrand and Lyon Hospitals. Secondary objectives were to determine the factors associated with non-compliance.

Results In 430 deceased patients included (176 in 2019 and 254 in 2020), the rate of non-compliance was 61.4% in 2019 and 59.1% in 2020 ($p=0.63$). In multivariable analysis, non-compliance was associated with immunosuppression status (OR 1.69, 95% CI (1.12 to 2.54), $p=0.01$) but was lower in intensive care unit (OR 0.54, 95% CI (0.36 to 0.82), $p=0.003$) and when the patient had visits from relatives (OR 0.41, 95% CI (0.22 to 0.75), $p=0.004$).

Conclusion In France, more than half of WWLST decisions do not comply with the law. The COVID-19 pandemic did not increase this non-compliance rate. Further studies are needed for a better understanding of the mechanisms underlying non-compliance with WWLST decision-making procedure.

Trial registration number NCT04452487.

INTRODUCTION

In intensive care unit (ICU), decisions to withhold or withdraw life-sustaining

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Collegiality of caregivers is a necessary condition for deciding on withholding or withdrawing life-sustaining treatment (WWLST).

WHAT THIS STUDY ADDS

- ⇒ In France, more than half of WWLST decisions do not comply with legal provisions.
- ⇒ The COVID-19 pandemic did not increase this non-compliance rate.
- ⇒ Non-compliance with WWLST decision-making procedure was associated with immunosuppression status but was significantly lower in intensive care and when the patient had visits from relatives.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ A better understanding of the mechanisms underlying non-compliance with WWLST decision-making procedures would enable us to propose interventions to improve the management of patients in palliative situations.
- ⇒ Emerging organising committees could reduce the rate of non-compliant WWLST decision-making procedures.

treatment (WWLST) concern almost 12% of hospitalised patients and 90% of patients who die.¹ Outside ICU, they concern about 50% of patients who die in hospital.² In France, since 2005, the laws on patients' rights at end of life (EOL) have recognised the need to avoid 'unreasonable obstinacy' and encourage ethical reflection. A decision regarding WWLST must respect the patient's wishes, ideally declared in advance directives (AD).^{3 4}

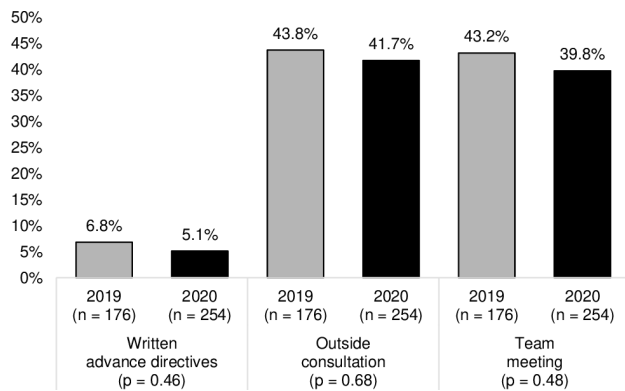


Figure 1 Procedural criteria for deciding to withhold or withdraw therapy, by period (2019 and 2020).

When the patient is unable to express his wishes and without any AD, the decision is taken by a physician following a collegial procedure. The law requires (1) consultation between members of the care team, (2) the opinion of at least one external physician and (3) a written summary of the procedure to be recorded in the patient's file. This provision is designed to guarantee compliance with the different ethical principles and restrains reversion to overly paternalistic medical attitudes. However, in daily practice, the prescribed procedure is not always followed.^{2 5}

The COVID-19 epidemic was an exceptional health situation strained human, therapeutic and material resources. It caused a disorganisation of the health system owing to the rapid saturation of care services and the exhaustion of personnel, who risked losing sight of the usual reference points when making decisions, particularly concerning WWLST.^{6 7} Several expert editorials have been published warning of this threat.^{8 9}

However, no work had yet explored the impact of the COVID-19 pandemic on compliance with the procedures governing WWLST decisions. The aim of our study was to assess how closely the procedures for making WWLST decisions in EOL patients were followed during the pandemic, compared with previously and secondary to determine the factors associated with non-compliance with the procedures for making WWLST decisions.

METHODS

This was a retrospective comparative multicentre study on the University Hospital of Lyon and Clermont-Ferrand. It followed the STROBE (STrengthening the Reporting of Observational studies in Epidemiology) recommendations for good clinical research practice (online supplemental file).

The main objective of our study was to compare the rate of non-compliance with WWLST decision-making procedure in EOL patients between the

COVID-19 pandemic period from March to June 2020 and an earlier control period from March to June 2019.

The secondary objectives were to determine the factors associated with non-compliance with WWLST decision-making procedure.

All adult patients, with or without COVID-19, who died at the Clermont-Ferrand University Hospital in the departments of ICU, internal medicine, postemergency medicine, and infectious diseases, and at the Lyon University Hospital in the departments of geriatrics, ICU and pneumology, were included. Patients who died after cardiac massage or whose diagnosis was brain death were excluded because no WWLST can be expected.

The list of deceased patients, data on ward characteristics, patient characteristics and the WWLST decision-making procedure were collected from the hospital's computerised medical records department.

Non-compliance with the WWLST decision-making procedure was defined as either the absence of any written AD from the patient combined with the absence of any written opinion from an external physician, or summary of a collegial discussion in the medical record.

The clinical data collected for the patient were: age, sex, reason for admission COVID-19 infection, comorbidities use of vasopressive drugs, invasive ventilation, renal replacement therapy during hospitalisation in the ICU, dependency score (Katz scale) length of hospitalisation, the presence of a mobile palliative care team and the reason for its visit visitors and their relationship to the patient, the presence of a surrogate and his or her relationship to the patient, presence in the patient's medical file of a written summary of the collegial WWLST discussion, existence of written AD left by the patient and the number of written opinions from external physicians.

Statistical analysis was performed using Stata software (V.15; StataCorp). All tests were two sided, with an alpha level set at 5%. Categorical data are presented as the number of patients and associated percentages, and continuous data as the mean \pm SD or median (25th; 75th percentiles), depending on the statistical distribution. Patients were compared between the two periods (2019 and 2020) using the χ^2 test or the Fisher's exact test for the categorical variables, and using the Student's t test or the Mann-Whitney U test for the continuous variables. The rate of non-compliance with the procedures for WWLST decisions is presented with a 95% CI. Factors associated with non-compliance with WWLST decision-making procedure were studied with the statistical tests aforementioned. A multivariable logistic regression was performed, considering covariates according to the results of

univariate analysis and their clinical relevance. Results are presented as OR and 95% CI.

RESULTS

A total of 430 deceased patients were included in the study: 176 in 2019 and 254 in 2020; 270 in Clermont-Ferrand and 160 in Lyon. In the 2020 period, there were fewer ICU admissions but a higher proportion of patients treated with invasive ventilation, shorter hospital stays and fewer visits.

Non-compliance with the procedures for WWLST decisions was observed in 60.0% (258/430) of cases (95% CI: 55.2% to 64.7%) : 61.4% (95% CI:

53.7% to 68.6%) in 2019, compared with 59.1% (95% CI 52.7% to 65.2%) in 2020 ($p=0.63$). The proportions of the different WWLST decision-making procedural criteria did not differ between the two periods (figure 1).

In the univariate analysis, the factors associated with non-compliance with WWLST decision-making procedure were: being hospitalised at the Lyon Hospital, being hospitalised outside an ICU, having no visit and being immunosuppressed (table 1).

In the multivariable analysis, non-compliance with WWLST decision-making procedure was

Table 1 Factors associated with non-compliance with the procedures for decisions to withhold or withdraw treatment

	Compliance (n=172)	Non-compliance (n=258)	P value
City			0.002
Clermont-Ferrand	123 (71.5)	147 (57.0)	
Lyon	49 (28.5)	111 (43.0)	
Age (years)	72.9±13.6	73.8±15.4	0.53
Male sex	95 (55.2)	152 (58.9)	0.45
Reasons for admission			
Infection (including sepsis and septic shock)	83 (48.3)	122 (47.3)	0.84
Acute respiratory symptoms	79 (45.9)	121 (46.9)	0.84
Hepato-digestive symptoms	30 (17.4)	57 (22.1)	0.24
Cardiac symptoms	31 (18.0)	31 (12.0)	0.08
Uro-nephrotic symptoms	10 (5.8)	13 (5.0)	0.73
Metabolic disorders	6 (3.5)	12 (4.7)	0.56
Neurological symptoms	23 (13.4)	33 (12.8)	0.86
Traumatology	8 (4.7)	11 (4.3)	0.85
Other	23 (13.4)	48 (18.6)	0.15
Organ failure	160 (93.0)	234 (90.7)	0.39
COVID-19 infection	35 (20.3)	41 (15.9)	0.24
Comorbidities	161 (93.6)	242 (93.8)	0.94
Diabetes	34 (19.8)	49 (19.0)	0.84
High blood pressure	82 (47.7)	111 (43.0)	0.34
Heart failure	31 (18.0)	37 (14.3)	0.31
Chronic renal failure	24 (14.0)	29 (11.2)	0.40
Respiratory failure	14 (8.1)	30 (11.6)	0.24
Cirrhosis	13 (7.6)	19 (7.4)	0.94
Immunosuppression	68 (39.5)	133 (51.6)	0.01
Other	38 (22.1)	43 (16.7)	0.16
Dependency			0.40
Total	16 (9.3)	30 (11.6)	
Partial	74 (43.0)	95 (36.8)	
No	82 (47.7)	133 (51.6)	
Hospitalisation in ICU	111 (64.5)	126 (48.8)	0.001
Hospital stay (days)	7 (3; 13)	6 (2; 13)	0.55
Visits	154 (89.5)	208 (80.6)	0.01
Surrogate	77 (44.8)	129 (50.0)	0.29
Intervention of MPCT	11 (6.4)	18 (7.0)	0.81

Data are presented as the number of patients (percentages), mean ±SD or median (25th; 75th percentiles).

ICU, intensive care unit; MPCT, mobile palliative care team.

Short report

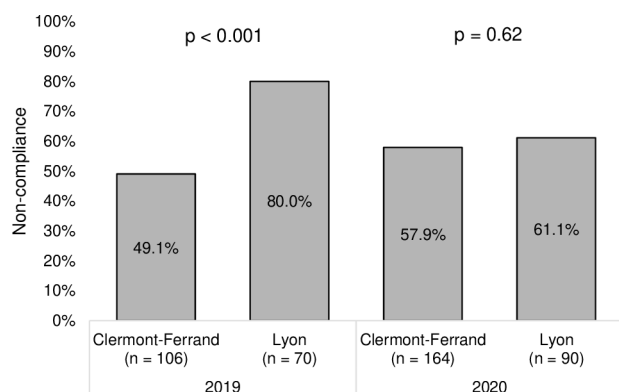


Figure 2 Non-compliance with the procedure for withholding or withdrawing life-sustaining treatment, by period (2019 and 2020) and city (Clermont-Ferrand and Lyon).

associated with immunosuppressed status (OR 1.69, 95% CI 1.12 to 2.54, $p=0.01$) but was significantly reduced when hospitalised in an ICU (OR 0.54, 95% CI 0.36 to 0.82, $p=0.003$) and when there were visits (OR 0.41, 95% CI 0.22 to 0.75, $p=0.004$).

There was a significant interaction between city and year on the non-compliance with WWLST decision-making procedure ($p=0.004$). It decreased in Lyon (80.0% in 2019 and 61.1% in 2020, $p=0.01$) (figure 2).

The difference in non-compliance by type of hospitalisation observed in 2019 was not found in 2020 (figure 3).

DISCUSSION

This work shows a high rate of non-compliance with WWLST decision-making procedures in France despite successive laws over the last 20 years. This rate was lower in ICU. The COVID-19 pandemic did not worsen non-compliance and even favoured organisation of these procedures in certain hospital structures, which reduced the non-compliance rate.

France does have a law in 2005 that precisely lays down the procedures for making WWLST

decisions. We, therefore, hypothesise that the main reason for this high rate of non-compliance is not any physicians’ unawareness but probably a lack of procedures practice.² Intensivists regularly perform these procedures because of high death rate in the ICU. The success of the Lyon ethical and palliative care committee is probably linked to the reminder of the procedures. The literature reports contrasting results on the impact of ethical committees in WWLST.^{10 11} However, the value of a palliative care team has been reported.^{12 13} This impact was particularly notable in wards where WWLST decisions were infrequent and which often showed a high rate of non-compliance.

Interestingly, having visits from friends and family was associated with more compliance with WWLST decision-making procedures. The presence of such visitors elicits a need for explanations and justifications for the patient’s management.¹⁴ This acts as a reminder for physicians to comply with WWLST decision-making procedures. By contrast, immunosuppression was associated with non-compliance. Immunosuppressed status is indicative of severe chronic disease often associated with a poor prognosis.¹⁵ EOL in this case is most often predictable, prompting physicians to consider the situation as unequivocal, and the collegial part of the WWLST decision as unnecessary.

This work has some limitations. First, our study was retrospective. However, a prospective study was not possible because we wanted a pre-COVID-19 control group. Second, the data collection was based on the traceability of information in the patient’s medical and nursing records. Any information not written down was considered irrelevant. All data collection in clinical research is based on this principle. Nevertheless, procedures might have been carried out that were not recorded in writing by the physician or the carer. Finally the Lyon ethical and palliative care committee was created in view of the critical nature of the health

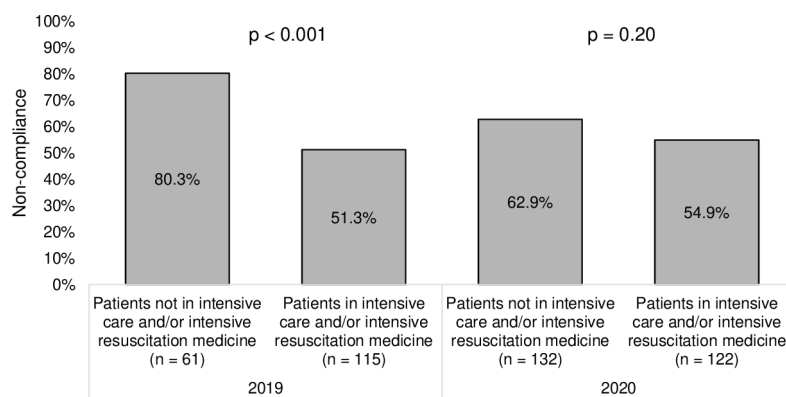


Figure 3 Non-compliance with the procedure for withholding or withdrawing life-sustaining treatment, by period (2019 and 2020) and intensive care (yes or no).

situation. It would be interesting to explore this sustainability and this long-term impact.

CONCLUSION

The rate of non-compliance with WWLST decision-making procedures in France, despite legal prescriptions in force for the last 20 years, was very high, though lower in ICU and when the patient received visits. Despite fears, the COVID-19 pandemic did not increase non-compliance. Further studies are needed to gain a better understanding of the mechanisms underlying non-compliance with WWLST decision-making procedures.

Twitter Virginie Guastella @guastella

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and this was a retrospective comparative multicentre study on the University Hospital of Lyon and Clermont-Ferrand. It received a favourable opinion from the local ethical committee CPP Sud-Est VI: 2020/CE 24. Because patients had already passed away. All adult patients, with or without COVID-19, who died at the Clermont-Ferrand University Hospital in the departments of ICU, internal medicine, postemergency medicine, and infectious diseases, and at the Lyon University Hospital in the departments of geriatrics, ICU and pneumology, were included.

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ORCID iD

Virginie Guastella <http://orcid.org/0000-0002-5712-8887>

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