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

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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}

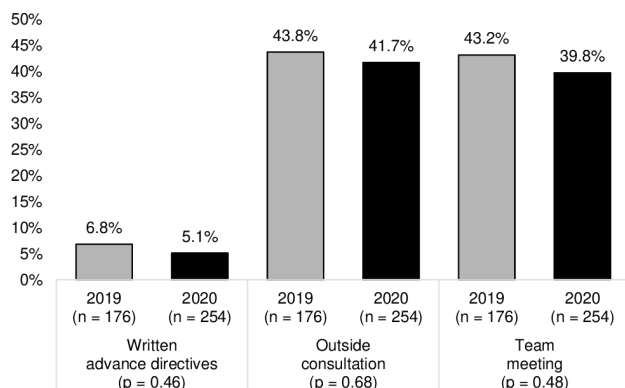


Figure 1 Procedural criteria for deciding to withhold or withdraw therapy, by period (2019 and 2020).

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

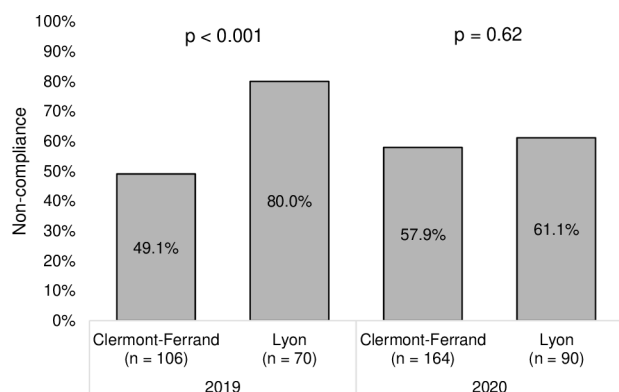


Figure 2 Non-compliance with the procedure for withholding or withdrawing life-sustaining treatment, by period (2019 and 2020) and city (Clermont-Ferrand and Lyon).

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

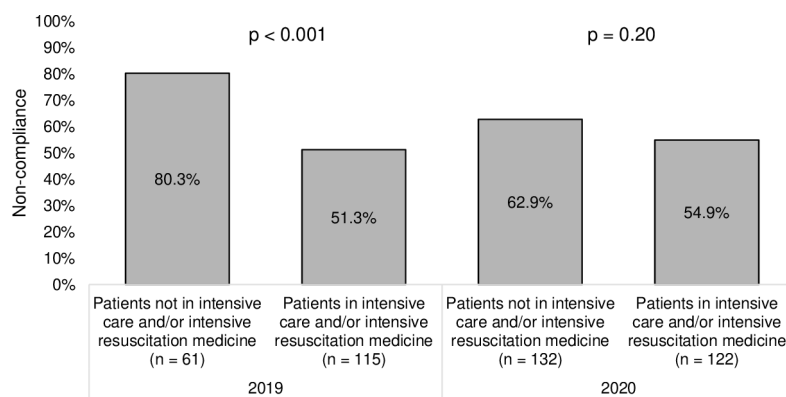


Figure 3 Non-compliance with the procedure for withholding or withdrawing life-sustaining treatment, by period (2019 and 2020) and intensive care (yes or no).

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.

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Contributors All authors are approved the manuscript and participated sufficiently in the work. VG, CL and AL made a substantial contribution to the concept and design of the work; AL, PM, AV, SW contributed substantially to the collection of the data. VG, CL, AL and EPC contributed to the analysis of the data. VG, CL and AL have critically revised the manuscript for important intellectual content.

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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.

Provenance and peer review Not commissioned; internally peer reviewed.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	6-7
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7
Bias	9	Describe any efforts to address potential sources of bias	NA
Study size	10	Explain how the study size was arrived at	NA
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	8
		(c) Explain how missing data were addressed	NA
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	NA
		(e) Describe any sensitivity analyses	NA

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-10
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	10-12
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	NA
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	NA
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10-12
		(b) Report category boundaries when continuous variables were categorized	NA
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12-15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15-16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.