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Outcome in patients perceived as receiving excessive care across different ethical climates: a prospective study in 68 intensive care units in Europe and the USA

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Abstract

Purpose: Whether the quality of the ethical climate in the intensive care unit (ICU) improves the identification of patients receiving excessive care and affects patient outcomes is unknown.

Methods: In this prospective observational study, perceptions of excessive care (PECs) by clinicians working in 68 ICUs in Europe and the USA were collected daily during a 28-day period. The quality of the ethical climate in the ICUs was assessed via a validated questionnaire. We compared the combined endpoint (death, not at home or poor quality of life at 1 year) of patients with PECs and the time from PECs until written treatment-limitation decisions (TLDs) and death across the four climates defined via cluster analysis.

Results: Of the 4747 eligible clinicians, 2992 (63%) evaluated the ethical climate in their ICU. Of the 321 and 623 patients not admitted for monitoring only in ICUs with a good ($n = 12$, 18%) and poor ($n = 24$, 35%) climate, 36 (11%) and 74 (12%), respectively were identified with PECs by at least two clinicians. Of the 35 and 71 identified patients with an available combined endpoint, 100% (95% CI 90.0–1.00) and 85.9% (75.4–92.0) ($P = 0.02$) attained that endpoint. The risk of death (HR 1.88, 95% CI 1.20–2.92) or receiving a written TLD (HR 2.32, CI 1.11–4.85) in patients with PECs by at least two clinicians was higher in ICUs with a good climate than in those with a poor one. The differences between ICUs with an average climate, with ($n = 12$, 18%) or without ($n = 20$, 29%) nursing involvement at the end of life, and ICUs with a poor climate were less obvious but still in favour of the former.

Conclusion: Enhancing the quality of the ethical climate in the ICU may improve both the identification of patients receiving excessive care and the decision-making process at the end of life.

Keywords: Perceived excessive care, Ethical climate, Decision-making, Interdisciplinary collaboration, Patient outcomes, Treatment-limitation decisions

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Introduction

Life supporting therapy in intensive care units (ICUs) has been increasingly offered to patients with poor long-term prognoses [1, 2], including those with advanced, end-stage organ dysfunction or a poor functional status [3–5]. While such therapies should not automatically be considered as non-beneficial, they should be provided only to well-informed patients or relatives in accordance with their preferences and values, and only if treatment intensity remains proportional to the expected outcome [6, 7]. Nevertheless, one in three deaths occurs during or shortly after ICU treatment [2], frequently following disproportionate levels of care [8–13].

An ethically-based clinical decision-making process has to rely on both individual perceptions and objective criteria, followed by interdisciplinary discussions that enrich the process for the benefit of the patient. However, expressing a perception of excessive care (PEC) to colleagues, and more specifically to senior ones, necessitates a safe climate in which clinicians are empowered to speak up and in which they feel that their opinion is valued and subsequently integrated into the decision-making process [14]. In addition to enhancing trust and cohesion in a team, such a climate may also reduce uncertainty in decision-makers by favoring intra- and interdisciplinary transfer of knowledge, experience and values [14]. Several studies have already shown that concordant prognostic estimates [15, 16] or perceptions of inappropriate [17] or futile care [18] by two clinicians may be considerably more predictive about the patient's short- and long-term outcomes than usually thought. However, whether the quality of the ethical climate prevailing in a unit further improves the identification of patients receiving excessive care, and impacts on patient outcomes and written treatment-limitation decision (TLD), is unknown.

The objectives of the current multicenter study were to assess whether the quality of the ethical climate in an ICU is associated with the prognostic value of PEC(s) with regard to patients' one-year outcomes and with the time from PEC(s) until written TLD during ICU stay or death. We hypothesized that the better the ethical climate, the more the PEC(s) would be predictive about patients' one-year outcomes and the shorter the time until written TLD or death.

Methodology

This study was approved by the ethics committees of all participating centers and the Danish National Health Authority. Informed consent was required in all countries to collect the one-year outcomes. The protocol, questionnaires and case-report form are available in the electronic supplementary material (ESM 1).

Take-home message

Enhancing the quality of the ethical climate in the ICU may improve both the identification of patients receiving excessive care and the end-of-life decision making process.

Study design and center recruitment

This 28-day observational study was conducted in 12 European countries and the United States. National coordinators and local investigators were recruited from the Ethics Section of the European Society of Intensive Care Medicine, the APPROPRICUS study group [8] and letters sent to experts in communication and end-of-life care in the ICU. National coordinators were expected to recruit four centers in their country, translate the questionnaires into their own language using the Brislin method [19], obtain ethics committee approval and assist the local investigators in their data collection and data quality tasks. Local investigators arranged study initiation meetings in their ICUs to enhance clinicians' participation, recruited patients after having obtained informed consent and recorded data in a dedicated case-report form on the www.DISPROPRICUS.be website.

Data collection instruments and definition of combined endpoint

Country, hospital, ICU and clinician characteristics are reported in the ESM 2. Hospital and ICU characteristics were collected by the local investigators between March and May 2014. Country-specific health variables were retrieved from a prior publication [20]. In April and May 2014, clinicians in the participating ICUs completed questionnaires on personal characteristics, working conditions and the ethical climate prevailing in their units using the ethical decision-making climate questionnaire (EDMCQ) [14]. This questionnaire consists of 35 items with four- or five-point Likert scale options; 11 items are on end-of-life care practices; 11 on interdisciplinary reflection, collaboration, and communication and 13 on leadership skills of senior doctors. The theoretical framework and the validation of this instrument can be found in a previous publication [14].

Daily, during the 28 day study period (between May 4 and July 4, 2014), the clinicians anonymously completed a questionnaire about their perceptions of disproportionate care for each of their patients. Disproportionate care was defined as care that is no longer consistent with the expected survival or quality of life (either "too much" or "not enough" care), or that is provided against the patient's or relatives' wishes. Questionnaire completion required less than 5 min per patient per day, when care was perceived as disproportionate, and less than 2 min

otherwise. ICU mortality and length of stay were collected in all patients admitted in the ICU; those already admitted prior to the study and those newly admitted during the study period. The characteristics reported in the ESM 2 were collected in patients admitted for reasons other than monitoring only during the study period. Categorization was left at the discretion of the attending physician. Written TLDs were ascertained by chart review.

Because staying at home with a good quality of life is highly valued by patients, the combined patient outcome in this study was defined as dead, not at home or a utility score < 0.5 at 1 year. This endpoint was defined during a study meeting with the national coordinators at the European Society of Intensive Care Medicine congress in Barcelona on September 30th 2014, approximately one year prior to data collection. Patients admitted for reasons other than monitoring only who were discharged alive, or their families, were contacted by telephone or mail one year after the ICU stay. The interviewer collected vital status, place of residence, and health-related quality of life using the EuroQoL-5D questionnaire [21], with conversion of each health state into a utility index (range -0.1584 to 1.000). This questionnaire measures health in five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels: no problems, moderate problems or severe problems. Therefore, patients can be classified into 1 of 243 possible health states, which is converted into the corresponding utility index (range -0.1584 to 1.000), indicating the preference of being in a health status. A utility index < 0.5 corresponds with severely compromised quality-of-life on at least one of the five dimensions. Although quality-of-life may be preferentially evaluated from the patient, for some older patients proxies may provide the most reliable information [22].

Data analysis

Ethical climates: factor and cluster analysis

Using the clinicians' answers to the 35 EDMCQ items, the data were first reduced via exploratory and confirmatory factor analysis to seven latent variables, also called factors [14]. The average score across clinicians for each factor in a given ICU was used as input for the cluster analysis at ICU level (ESM 2). Such analyses seek to minimize the similarity of ICUs within climates and maximize the dissimilarity of ICUs between climates. In particular, we used the partitioning around medoids (PAM) algorithm to classify the different climates into a pre-specified number of clusters. This algorithm was chosen in view of its robustness to outliers and noise [23]. Pearson's chi square tests were used for comparing categorical variables between climates and Kruskal–Wallis tests (or

ANOVA tests where appropriate) for comparing continuous variables. Results were expressed as number (%) and median (25–75th percentiles), respectively.

Differences in patients' combined endpoint at one year across ethical climates

To simplify the analysis only perceptions of excessive (“too much”) care were taken into account in the current study. As PEC by a clinician alone was only moderately predictive of the patient's combined outcome compared to no PEC across all climates (ESM 2), and previous publications have highlighted the importance of concordance between two clinicians [15–18], we compared the probability of attaining the combined endpoint for patients with PECs by at least two clinicians between the ethical climates. For practical reasons, “PECs by at least two clinicians” is referred to as “concordant PECs” throughout the manuscript. Differences in combined endpoint in patients without and with concordant PECs between and within climates were compared with a Pearson's Chi square and a Fisher's exact test, respectively.

Differences in time until death and treatment limitation decisions across ethical climates

Time until identification of patients with concordant PECs, and from concordant PECs until written TLD or death were compared using (cause-specific) hazard ratios, obtained via Cox regression (accounting for competing risks) [24]. The cause-specific hazard of an event expresses the instantaneous risk of that event at a given time for patients who are still alive in the ICU at that time and have not previously experienced that event [24]. To better explore the so-called “self-fulfilling prophecy issue” (prognostication influenced by decision-making), we compared the risk of death in patients with concordant PECs in different decision-making scenarios (doctor–doctor, doctor–nurse, nurse–nurse) between and within climates.

Adjustment for case-mix, hospital and country characteristics

To adjust for differential case-mix, hospital and country characteristics between climates, we used inverse probability weighting based on propensity scores [25]. Here, the propensity score is the probability of being treated in one's own climate, as obtained using a multinomial model based on patient, hospital and country characteristics. Adjustment based on propensity scores has the advantage, relative to other adjustment methods, of preventing model extrapolation, when climates are very different in terms of these characteristics [25]. However, one concern about adjustment for case-mix is that it may eliminate the effects of potential differences in admission policy (which affects case-mix) between climates.

Therefore, we considered the unweighted results as our principal results. These are expressed as proportions and (cause-specific) hazard ratios (HR) along with 95% confidence intervals (95% CI). Two-sided *P* values were considered significant at the 0.05 level. Priority was given to comparisons between the good and the poor ethical climates (see results) in order to reduce type I errors. We refer to the ESM 2 for a more detailed methodology.

Results

Ethical climates

Of 4747 clinicians working in 68 ICUs in Belgium, Czech Republic, Denmark, France, Germany, Greece, Hungary, Italy, Portugal, United Kingdom, Sweden, the Netherlands and the United States, 2992 (62.6%) completed the EDMCQ (Fig. 1).

The cluster analysis based on the average scores of the seven factors identified during the validation of the EDMCQ [14] yielded four different meaningful, mutually exclusive ethical climates. Visual inspection of the scree plot (ESM 2) revealed that clustering into three clusters would drastically increase the total intra-cluster variation (as opposed to using four clusters), while clustering into five clusters would only minimally decrease the total intra-cluster variation [23]. These climates were denominated by experts in intensive care (DB, JD), psychology (BV, SV) and ethics (RP) as: good, average with⁽⁺⁾ and without⁽⁻⁾ nurses' involvement at end-of-life, and poor (Fig. 2, ESM 2). According to clinicians working in a good climate, leadership by senior doctors is active and facilitates interdisciplinary reflection and decision-making overall. This climate is also characterized by mutual respect, which is pre-requisite to facilitating interdisciplinary reflection and ethical awareness [14]. Within the average⁽⁺⁾ climate, clinicians perceive that senior doctors empower nurses to share interdisciplinary decision-making, mainly at end-of-life. Even though clinicians working in an average⁽⁻⁾ climate believe that their senior doctors are able to make decisions, they do not find them promoting nurse involvement in decision making at end-of-life. Finally, clinicians working in a poor climate perceive a need for improvement in all of these factors.

The ICU, clinician, and patient characteristics for each climate are reported in ESM 2. The average⁽⁻⁾ and poor climates were more prevalent in Central and Southern European countries ($P < 0.001$); however, 10 of the 24 (41.7%) ICUs with a poor climate were situated in Western Europe and the United States. The ICU experience of clinicians was similar across climates, however, the number of participating doctors was higher in the average⁽⁻⁾ and poor, compared to the other two climates. The average⁽⁻⁾ and poor climates were also associated with a slightly higher number of admitted patients with

severe underlying comorbidities and with greater use of advanced and prolonged life-supporting treatments in the post-operative setting, compared to the other climates.

Differences in patients' combined endpoint at one year across ethical climates

Of the 1761 patients admitted for more than only monitoring with data concerning time until event available (Fig. 1), 74 (4.2%) patients were perceived as receiving excessive care by two clinicians, and 107 (6.1%) by more than two clinicians, resulting in 36 (11.0%), 50 (7.2%), 21 (18.0%) and 74 (12.0%) patients with concordant PECs from the good to the poor climate, respectively. Excessive care was perceived by these clinicians as being provided against the patients' or relatives' wishes in 20 (55.5%), 25 (50.0%), 11 (52.4%) and 41 (55.4%) ($P = 0.94$) of these patients.

The differences in the patients' combined outcomes across ethical climates are reported in Table 1. The probabilities of attaining the combined endpoint in patients without concordant PECs was 53.5% (95% CI 46.8–60.2), 59.1% (54.6–63.6), 64.0% (53.1–74.9) and 51.8% (47.3–56.3) from good to poor climate, respectively ($P = 0.057$, difference between good and poor climate, $P = 0.74$). These probabilities increased to 100% (90.0–100), 95.6% (84.3–98.9), 94.7% (70.6–99.3) and 85.9% (75.4–92.0) in patients with concordant PECs ($P = 0.047$, difference between good and poor climate, $P = 0.020$).

Differences in time until death and treatment limitation decisions across ethical climates

We found no difference in incidence or in time from admission until concordant PECs between the good and the poor climates; approximately 11% of the patients were identified with concordant PECs after 14 days in both climates (Fig. 3a).

The risk of death in patients with concordant PECs was statistically significantly higher (HR 1.88, 95%CI 1.20–2.92) in the good compared to the poor climate. The median time until death in patients with concordant PECs was 5 days (2–18) vs. 14 (6–34) days ($P = 0.008$), respectively. The difference between the average climates and the poor climate was less important, but still in favor of the average climates (Fig. 3c). The risk of death in the good climate was higher in patients with PECs by two or more doctors than in those with PECs by two or more nurses (HR 3.13, 95% 1.19–8.23), with the risk of death in patients with PECs by at least one nurse and one doctor being intermediate. There was no evidence of such a difference in risk of death in the poor climate (HR 0.74, 95% 0.29–1.86) (ESM 2).

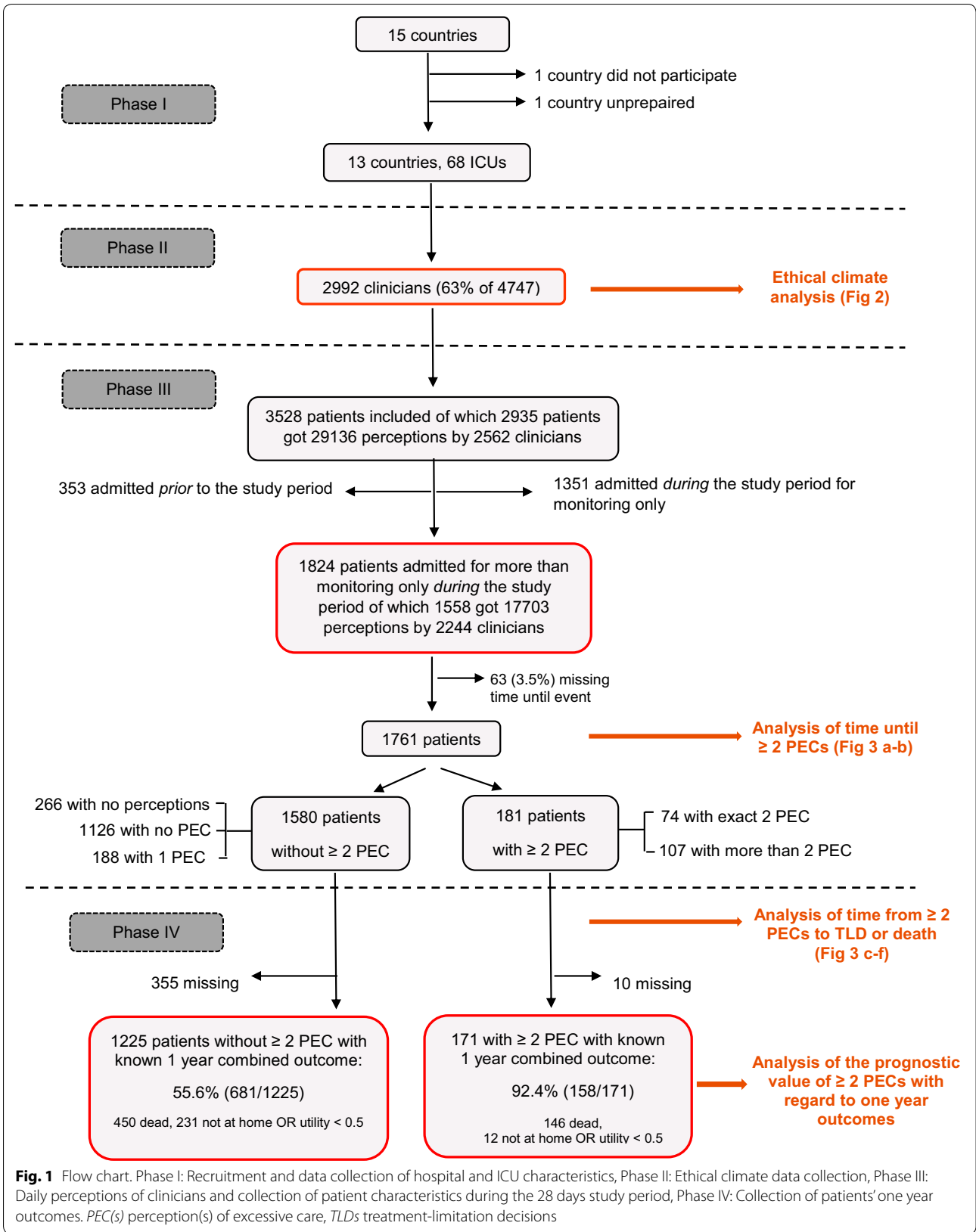


Fig. 1 Flow chart. Phase I: Recruitment and data collection of hospital and ICU characteristics, Phase II: Ethical climate data collection, Phase III: Daily perceptions of clinicians and collection of patient characteristics during the 28 days study period, Phase IV: Collection of patients' one year outcomes. *PEC(s)* perception(s) of excessive care, *TLDs* treatment-limitation decisions

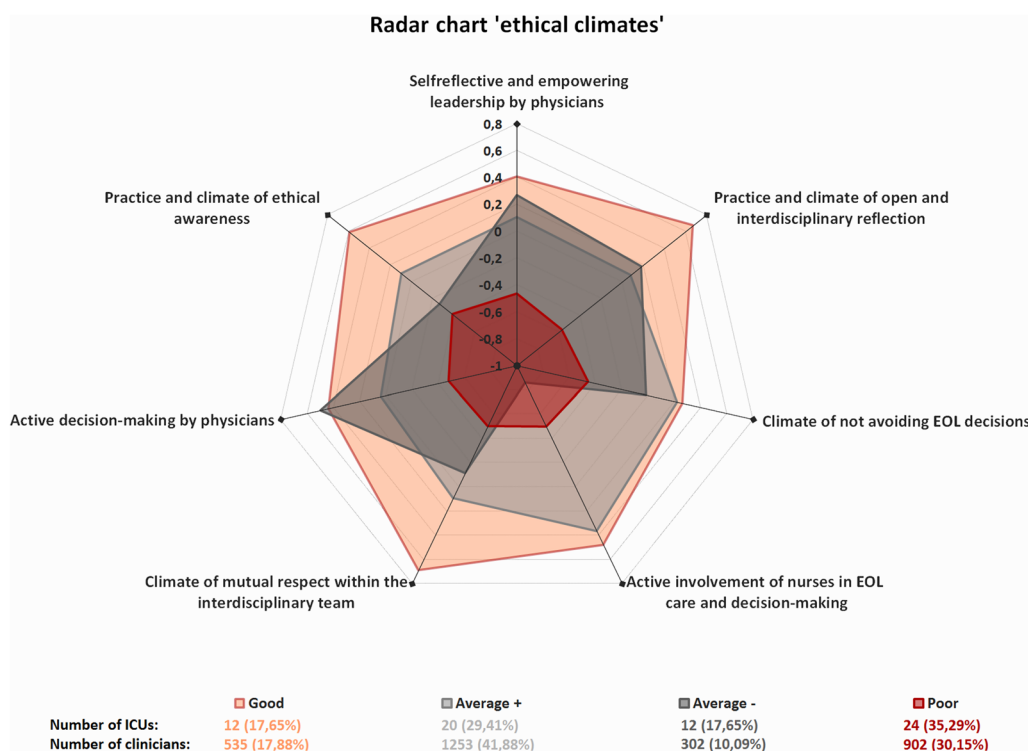


Fig. 2 Ethical climates. Factor and cluster analysis were used to obtain mutually exclusive climates. Factor analysis attributes and aggregates the 35-item ethical decision-making climate questionnaire into seven factors for each clinician, which describe different aspects of the ethical decision-making climate as perceived by that clinician. These were subsequently averaged across clinicians to obtain seven factor scores per ICU [14]. A cluster analysis based on these averages scores identified four meaningful ethical climates; good, average with⁽⁺⁾ and without⁽⁻⁾ involvement of nurses at end-of-life (EOL), and poor. The figure visualizes the average factor scores in clinicians per climate. Larger values indicate better agreement with the climate expressed by the corresponding factor. More detailed information can be found in the ESM 2

Table 1 Differences in patients’ one-year outcomes across ethical climates in patients with and without concordant PECs

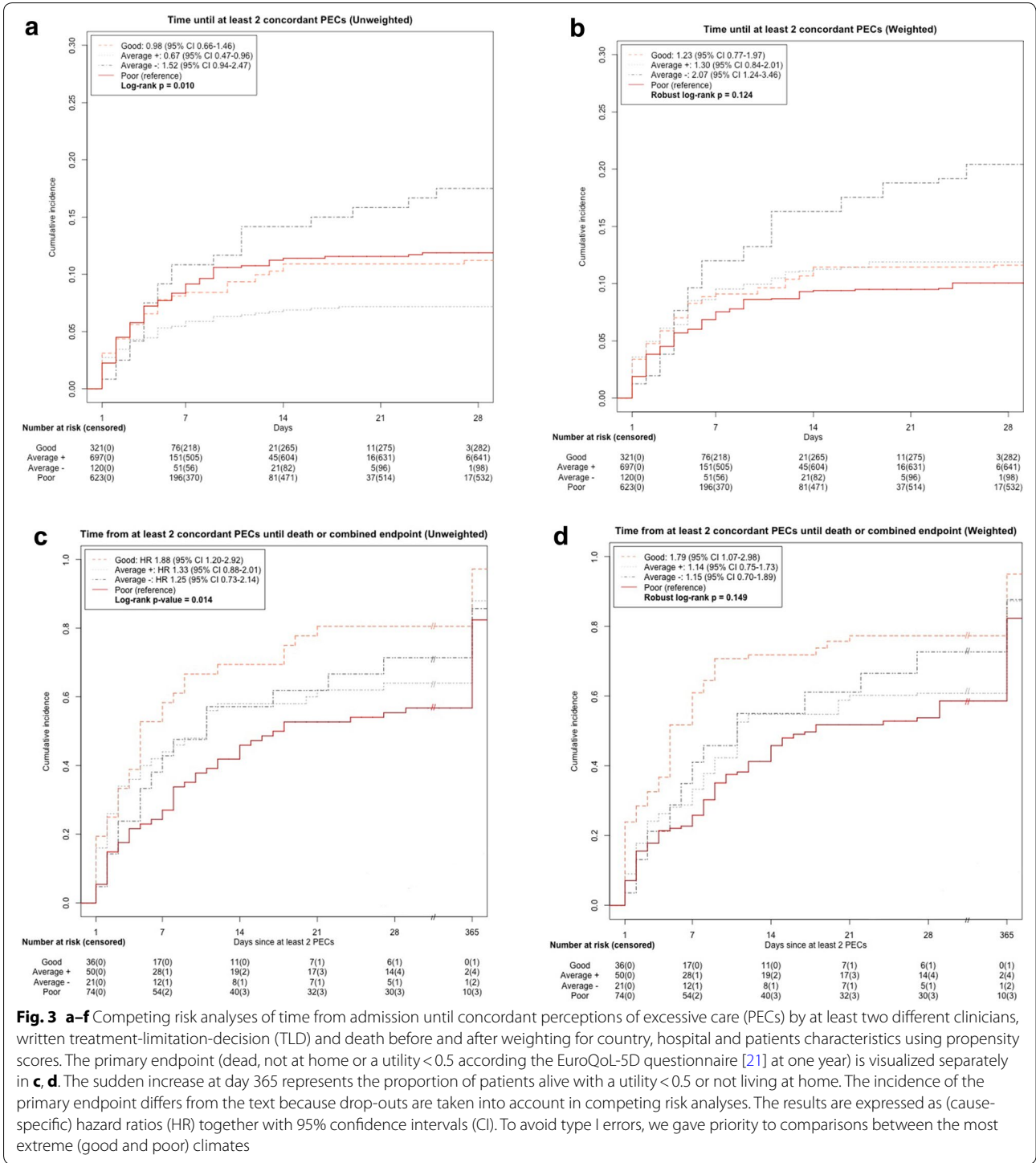
	Ethical climate				P value overall	P value good vs. poor climate
	Good	Average ⁽⁺⁾	Average ⁽⁻⁾	Poor		
Patients without concordant PECs (n= 1225)	n = 215	n = 464	n = 75	n = 471		
Combined endpoint ^a	115 (53.5%)	274 (59.1%)	48 (64.0%)	244 (51.8%)	0.057	0.740
Dead	68 (31.6%)	175 (37.8%)	39 (52.0%)	168 (35.7%)		
Alive not at home or utility < 0.5	47 (21.9%)	99 (21.3%)	9 (12.0%)	76 (16.1%)		
Patients with concordant PECs (n= 171)	n = 35	n = 46	n = 19	n = 71		
Combined endpoint ^b	35 (100%)	44 (95.6%)	18 (94.7%)	61 (85.9%)	0.047	0.020
Dead	33 (94.3%)	41 (89.1%)	18 (94.7%)	54 (76.0%)		
Alive not at home or utility < 0.5	2 (5.7%)	3 (6.5%)	0 (0.0%)	7 (9.9%)		

After weighting to adjust for differential case-mix, hospital and country characteristics, the probability of attaining the combined endpoint in patients ^awithout and ^bwith concordant PECs was 56, 62, 60 and 55% ($P=0.26$, difference between good and poor climate, $P=0.82$) and 100, 93.9, 93.5 and 86.2% ($P=0.042$, difference between the good and the poor climate, $P=0.017$) from the good to the poor climate, respectively

Patients with concordant PECs had a higher chance of receiving a written TLD in the good compared to the poor climate (cause-specific HR 2.32, 95%CI 1.11–4.85) (Fig. 3e).

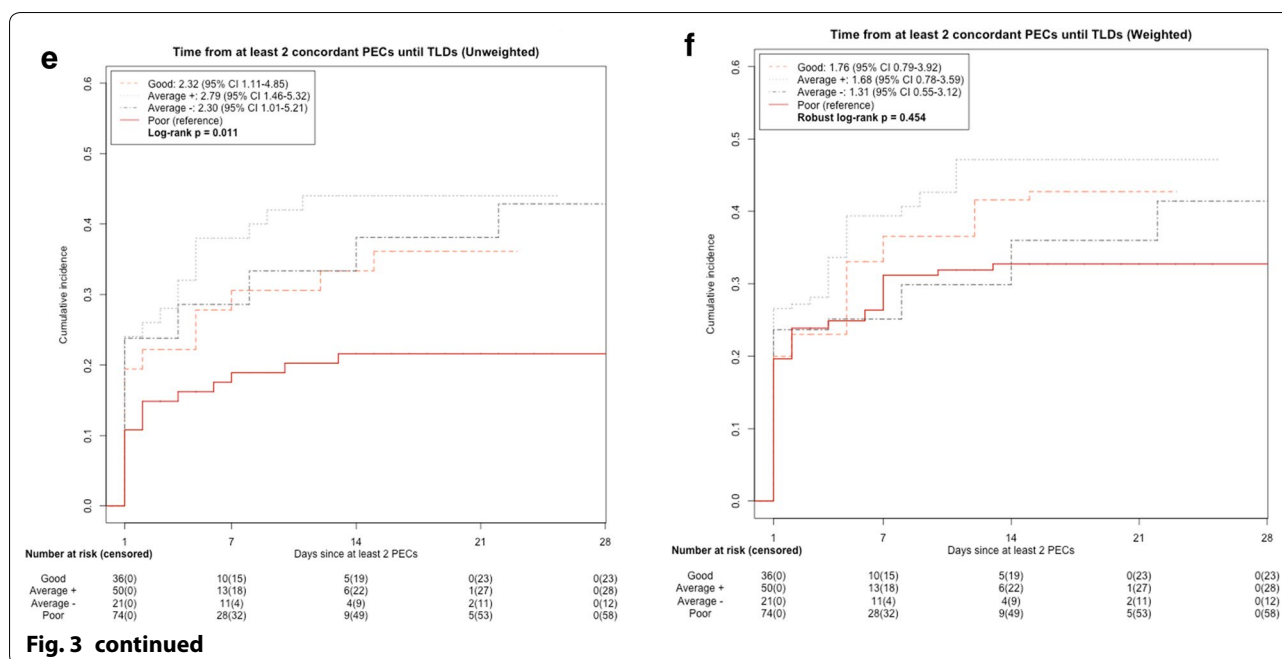
Adjustment based on propensity scores

After weighting to adjust for differential case-mix, hospital and country characteristics, the probability of attaining the combined endpoint in patients without



concordant PECs was 55.8% (48.2–63.1), 62.1% (56.5–67.4), 60.2% (47.4–71.7) and 54.8% (49.4–60.1) from good to poor climate, respectively ($P=0.26$, difference between good and poor climate, $P=0.82$). These probabilities increased in patients with concordant PECs to

100% (90.0–100), 93.9% (74.3–98.8), 93.5% (64.2–99.1) and 86.2% (72.0–93.8), respectively ($P=0.042$, difference between the good and the poor climate, $P=0.017$). The risk of death in patients with concordant PECs also remained higher in the good vs. the poor climate



(HR 1.79, 95%CI 1.07–2.98) (Fig. 3d). The median time until death was 5 (2–18) and 14 (7–30) days ($P = 0.026$), respectively. The risk of death in the good climate remained higher in patients with PECs by two or more doctors than in those with PECs by two or more nurses (HR 3.58, 95% 1.42–9.02), with the risk of death in patients with PECs by at least one nurse and one doctor remaining intermediate. There was no evidence of such a difference in risk of death in the poor climate (HR 1.58, 95% 0.45–5.55) (ESM 2).

However, we no longer found evidence of a difference in time until TLD between the good and the poor climates (cause-specific HR 1.76, 95%CI 0.73–3.92) (Fig. 3f).

Discussion

In this large, multicenter, prospective, ICU study, we found that concordant PECs by at least two clinicians were far more predictive about the primary composite endpoint of death, not living at home, or having poor quality of life one year after ICU admission, compared to absence of PEC. We found evidence of a difference in one-year outcomes, time until death and written TLD in patients with concordant PECs across the four ethical climates identified by our questionnaire. The evidence of a difference in time until written TLD disappeared after adjusting for differential case-mix, hospital and country characteristics.

In contrast to the study by Detsky et al. [16], clinicians in our study were not explicitly expected to provide prognostic estimates about the patients' outcomes.

We preferred to focus on the intuitive-heuristic more than the analytic-deductive part of the complex ethical decision-making process [26, 27], by asking clinicians whether they felt that the care provided to their patient on a specific day was consistent with the expected outcome in terms of survival and quality of life, and whether this amount of care was in line with the patient's or relatives' wishes. We also didn't focus on futile care, such as in the studies of Neville et al. [18], because this terminology presupposes a high degree of certainty concerning the final fatal prognosis, whereas nowadays technological innovation frequently excludes patients' spontaneous death in ICU [6, 7]. By doing so, we acknowledged uncertainty [26] (benefit vs. harm) and patient and family autonomy, as an integral part of the complex ethical decision-making process at the bedside [28]. Nevertheless, PEC was highly predictive about patients' one-year outcomes, more specifically when expressed by two or more than two clinicians.

Concordant PECs by at least two different clinicians were more predictive about the combined endpoint in the good compared to the poor ethical climate ($P = 0.028$). Patients with concordant PECs also had a higher risk of death and of receiving a written TLD in the good compared to the poor climate. The difference in endpoints between the average and the poor climates was less obvious, but still in favor of the former compared to the latter, thus objectively validating our EDMCQ instrument [14]. Unfortunately, we can neither exclude nor confirm self-fulfilling prophecy in the good climate. However, it is of note that it took about 14 days

to identify all patients with concordant PECs in both climates and, for half of these patients, another 5 days to die in the good vs. 14 days in the poor climate ($P=0.002$). In line with the results of the EDMCQ, this suggests that the decision to forgo life sustaining treatment in the good climate was not premature, and once excessive care was perceived by at least two clinicians, it occurred in a timely fashion. Furthermore, in a sub-analysis, we found no difference in risk of death between patients with concordant PECs by different professionals in the poor climate, as opposed to the good climate. This indicates that identification of patients with excessive care by doctors in the poor climate was not followed by active decision-making. In addition to, respectively, increasing the risk of prolonged suffering and complicated grief in patients and relatives [29, 30], decision-paralysis as a strategy to cope with prognostic uncertainty [8, 12, 31] may also induce moral distress and increase intention to leave in clinicians [6, 32–34]; a fact that is even more pertinent considering the high number of concordant PEC records perceived as violating the patient's or relatives' wishes in this study. After weighting for the specific case-mix within a hospital and country, only the risk of receiving a written TLD in the good compared to the poor climate was no longer significantly different. This may suggest that the quality of the ethical climate in an ICU is important in identifying patients receiving excessive care and in subsequently triggering the decision-making process at end-of-life, whereas formalizing that process via a written TLD seems more case-mix and culture dependent. This is in line with previous studies showing a huge variability in written TLDs between countries and ICUs [35].

The probability of dying or surviving with a poor quality of life at one year in patients without concordant PECs was 53.5, 59.1, 64.0 and 51.8% from good to poor climate, respectively, largely exceeding that of many malignancies [36]. Therefore, in line with the definition of disproportionate care [6, 8, 9], clinicians did not find poor prognosis sufficient by itself to lead to a PEC. Concordant PECs by at least two clinicians increased the probability of reaching the combined endpoint to 100% in the good, 95.6% in the average⁽⁺⁾ and 94.7% in the average⁽⁻⁾ climate, compared to 85.9% in the poor. Despite the poor prognosis we found a relatively low incidence of written TLDs within the 14 days in these patients; ranging from 20% in the poor to only 35% in the good and about 45% in average climates ($P=0.011$). Although caution in interpreting this result is required due to small sample size, these probabilities highlight the urgent need for improving advance-care planning before ICU admission [37], as well as triage and decision-making at end-of-life in ICU. This should more specifically be achieved via ethical climates that favor interdisciplinary reflection and

collaboration [6, 8, 14, 32, 38, 39], and early involvement of palliative care [30, 37, 40]. Our EDMCQ instrument may be used for that purpose [14, 32].

Our study has several limitations. First, the participating ICUs were not selected at random, which may have affected the external validity of our results. Second, inclusion of patients was left at the discretion of the attending doctor. However, except in the average⁽⁻⁾ climate (ESM 2), we found no evidence of a difference in ICU mortality rates or length of stay in the subgroup of patients admitted for monitoring only across climates, indicating that the attending doctors included patients in a similar way. We further minimized confounding bias by accounting for differences in case-mix, using inverse probability weighting based on propensity scores. Third, we did not use classical severity-of-illness scores in our analysis. However, in line with our primary objective, we preferred to include short- and long-term prognostic factors [4, 5] that are commonly used by clinicians during decision-making, rather than classical severity-of-illness scores which have never been validated for predicting long-term outcomes. Fourth, one has to keep in mind that the incidence of patients with concordant PECs is probably underestimated, as patients admitted prior to the study period and those who remained in ICU for longer than the study period (and were expected to reach more clinician concordance with time) were excluded from the analysis. Finally, although the ICU experience of clinicians was similar, we cannot exclude that the lower number of participating doctors in the good compared to the poor climate may have biased our results in favor of the latter, concealing even larger differences between the two.

Conclusion

Our results suggest that improving the quality of the ethical climate in ICU may favor the identification of patients receiving excessive care and the subsequent decision-making process at end-of-life. This may benefit the quality of the dying process in ICUs.

Electronic supplementary material

The online version of this article (<https://doi.org/10.1007/s00134-018-5231-8>) contains supplementary material, which is available to authorized users.

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Compliance with ethical standards

Conflicts of interest

DB reports grants from Gilead, Astellas, Fisher-Paykel, Baxter, Alexion and Fresenius Kabi outside the submitted work. KR reports honoraria from Alexion, outside the submitted work. MD reports grant from MSD and Jazz Pharma, personal fees from Astellas and Bristol-Myers Squibb, and non-financial support from Astellas, Bristol-Myers Squibb, Astute Medical, and Sanofi Aventis. EA reports grants and personal fees from Gilead, Alexion, MSD, Cubist and personal fees from Baxter, outside the submitted work. All other authors have no conflict of interest to report.

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