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Guidelines for withholding and withdrawing therapy in the ICU: impact on decision-making process and interdisciplinary collaboration

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ABSTRACT

Introduction: Interdisciplinary collaboration in end-of-life decision-making is challenging. Guidelines developed within the interdisciplinary team may help to clarify, describe, and obtain consensus on standards for end-of-life decision-making and care. The aim of the study was to develop, implement, and evaluate guidelines for withholding and withdrawing therapy in the intensive care unit.

Methods: An intervention study in two Danish intensive care units, evaluated in a pre-post design by a retrospective hospital record review and a questionnaire survey. The hospital record review included 1,665 patients at baseline (12-month review) and 897 patients after the intervention (6-month review). The questionnaire survey included 273 nurses, intensivists, and primary physicians at baseline and 229 post-intervention.

Results: For patients with therapy withdrawn, the median time from admission to first consideration on level of therapy decreased from 1.1 to 0.4 days (p = 0.03), and the median time from admission to a withdrawal decision decreased from 3.1 to 1.1 days (p = 0.02). Sixty-five percent of the participants who used the guidelines concerning end-of-life decision-making considered them helpful to high or very high extent. No significant changes were found in satisfaction with interdisciplinary collaboration or in withholding or withdrawing decisions being changed or unnecessarily postponed. The healthcare professionals' perception of the care following withdrawal of therapy increased significantly after implementation of the guidelines.

Conclusions: The study indicates that working with guidelines for withholding and withdrawing therapy in the intensive care unit may facilitate improvements in end-of-life decision-making and patient care, but further studies are needed to provide robust evidence.

Keywords: end-of-life, critical care, guidelines, withholding treatment, collaboration, decision-making.

INTRODUCTION

In modern healthcare, evidence-based medicine put into practice via guidelines is the main principle for promoting and ensuring high quality in patient care (1). Guidelines can be defined as "systematically devel-

oped statements to assist practitioners and patient decisions about appropriate health care for specific clinical circumstances" (2). Within the intensive care unit (ICU) researchers have examined the impact of working with guidelines in terms on mechanical ventilation (3, 4), sepsis (5), and sedation (6). In regard to end-of-life care, studies on the effect of guidelines implementation are limited, but related studies are have, among other things, examined the impact of an order form for withdrawal of

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life support (7), implementation of a strategy including both organisational changes and plans for communication within the care team and with patients and their families (8), and the use of ethics consultations in the ICU (9). Withholding therapy is defined as a decision not to start or increase a life-sustaining intervention and withdrawing therapy as a decision to actively stop a life-sustaining intervention that is presently being given (10). End-of-life practice varies between countries due to legal, cultural, and religious differences (10-12).

Some of the challenges in end-of-life care is connected with the interdisciplinary collaboration, including different views on the patient's recovery potential (13, 14), communication issues in the interdisciplinary team (15), and a lack of nurse participation in the decision-making process (16, 17).

Guidelines developed within the interdisciplinary team may help to clarify, describe, and obtain consensus on standards for endof-life decision-making and care, and thereby improve satisfaction with interdisciplinary collaboration and patient care.

Accordingly, the aim of this study was to develop, implement, and evaluate guidelines for withholding and withdrawing therapy in the ICU.

METHODS

The study was conducted in two regional Danish ICUs with 8 and 11 beds, respectively. At baseline end-of-life issues were occasionally discussed in the ICUs but were not a specific focus. The Danish Health Legislation (18) was unclear at some points regarding end-of-life decision making, inducing some uncertainty and differences in practice among healthcare professionals. The interdisciplinary collaboration was generally good, some discrepancies between nurses, intensivists, and primary

physicians were experienced when dealing with end-of-life decision making.

This prompted initiation of a study including different subprojects: investigation of baseline status for end-of-life decision-making through a hospital record review (19), interviews with nurses, intensivists, and primary physicians, and a questionnaire survey (20). Furthermore, three interdisciplinary audits were conducted in which the participants assessed patient cases and discussed quality goals for end-of-life decision-making.

In 2009, the Danish Association of Anaesthesiology and Intensive Care Medicine published guidelines for the "Ethical considerations on withholding or withdrawing therapy" (21); these guidelines however are not mandatory for the ICU staff to follow, and as they consist of a 96-page document. they are not useful as instructions in daily practice. Therefore, development of local guidelines for withholding and withdrawing therapy was planned in order to respond to the identified challenges. The guidelines were developed based on national and international literature, the Danish national guidelines (21), and the challenges and suggestions for improvement elucidated at the baseline surveys. The draft went through review phases among nurses, intensivists, primary physicians, and all relevant Heads of Departments; the guidelines were subsequently approved by the Heads of Departments of Anaesthesiology.

The guidelines (please see online supplement for full copy) consisted of the following five sections: A) short background on legal issues regarding end-of-life decision-making; the section was written in cooperation with an attorney from The National Board of Health; B) definitions and principles; C) issues regarding the decision-making process, such as who should be involved and what should be documented; D) agreements and practical advice regarding withholding and

withdrawing therapy; E) key recommendations regarding patient, relatives, and staff. The guidelines were published on the hospitals' on-line guideline systems (INFO-net) in May 2011, and were presented at staff meetings. E-mail notifications were sent to all nurses and intensivists. The Head of Departments backed the implementation as well as the relevance and necessity of the guidelines.

The effect of implementing guidelines for withholding and withdrawing therapy was evaluated 6 months after implementation through a hospital record review and a questionnaire survey. All patients who died in one of the ICUs or were discharged with treatment withheld or withdrawn between June 1st and November 30th 2011 were included in the hospital record review. Basic characteristics of patients who were discharged from the units with full therapy were also collected. The results were compared to baseline data from patients admitted to the two ICUs in 2008 (19).

The questionnaire related to different aspects of end-of-life practices, including applicability of the guidelines and was almost identical to a baseline questionnaire regarding end-of-life issues in Danish ICUs which was developed and validated in 2010 (20, 22). Five questions evaluating the guidelines were added. To prevent the questionnaire being too comprehensive, seven general questions about end-of-life issues (not relevant for evaluation of the guidelines) were removed.

The main end-point was the length of stay for patients with therapy withdrawn. With 117 patients at baseline, an expected 58 patients at evaluation, and with α 0.05 and β 0.80, the length of ICU stay should be reduced by 2 days (SD 4.4) to be statistically significant. Data were double-entered into EpiData (version 3.1), and descriptive and statistical analyses were performed using STATA 10.1. For comparing different staff

groups, the chi-square test was used for dichotomous and categorical data, and the Mann-Whitney U test and Kruskal-Wallis test were used for non-normally distributed continuous and ordinal data. Wilcoxon signed-rank test was used for paired analyses

According to Danish law, the study did not require permission from The Regional Ethics Committee, as confirmed by the Committee. Permission to conduct a hospital record review was granted from The Danish Data Protection Agency and The Danish National Board of Health. Permission to obtain and store code lists of staff for the questionnaire survey was granted from The Danish Data Protection Agency. All Heads of Departments gave permission to their staff to take part in the survey. All participants were informed that participation was voluntary, and that responses were anonymous. Permission to include data from the baseline questionnaire survey (20) and the hospital record review (19) was granted from Springer and Wiley.

RESULTS

Hospital record review. When comparing pre- and post-intervention data, no differences existed in the percentage of patients who died in the ICU, or in the proportion of patients who died while undergoing therapy, after therapy was withheld, or after therapy was withdrawn (*Table 1*).

For patients dying after therapy withdrawal, median length of stay from admission to first consideration on level of therapy decreased from 1.1 to 0.4 days and time from admission to withdrawal decision decreased from 3.1 to 1.1 days. A non-significant decrease was found in total length of stay (*Table 2*).

For patients in whom therapy was withdrawn, no differences existed in gender or

Table 1 - Levels of therapy. Comparison between hospital record reviews at baseline (12 months, 2008) and after guideline implementation (6 months, 2011).

	20	081	20	11	
	n	% ²	n	% ²	p^3
Total number of patients	1,665		897		
Patients discharged with					
Therapy active	1,401	(84.1)	743	(82.8)	0.43
Therapy withheld	68	(4.1)	42	(4.7)	0.48
Therapy withdrawn	20	(1.2)	19	(2.1)	0.08
Patients dying in the intensive care unit	176	(10.6)	93	(10.4)	0.87
Therapy still active	34	(19.3)	17	(18.3)	0.84
Therapy withheld	25	(14.2)	16	(17.2)	0.52
Therapy withdrawn	117	(66.5)	60	(64.5)	0.17

^{1.} Data from baseline hospital record review (ref. 19)

Table 2 - Comparison of background characteristics, lengths of stay, and severity scores between hospital record review at baseline (2008) and after guideline implementation (2011).

	200	8 ¹	201	1	
	\mathbf{n}^2	median	\mathbf{n}^2	median	\mathbf{p}^3
All patients discharged with active therapy	1,401		743		
Gender, Female (%)	673 (48)		319 (43)		0.03
Age	1401	63	743	65	0.01
Length of stay in ICU (median days)	1401	0.92	743	0.92	0.22
APACHE II ⁴	582	17	328	20	< 0.001
SAPS ⁵	578	33	327	35	0.03
SOFA 1 ⁶	487	5	329	5	0.71
SOFA 2 ⁶	491	5	330	5	0.21
Patients who died in the ICU	176		93		
Gender, Female (%)	63 (36)		41 (44)		0.18
Age	176	72	93	71	0.80
Length of stay in ICU (median days)	176	1.69	93	1.21	0.43
APACHE II ⁴	97	25	54	27	0.008
SAPS ⁵	97	48	54	53.5	0.03
SOFA 1 ⁶	91	8	54	7	0.93
SOFA 2 ⁶	92	12	54	11	0.19
Died. Therapy active	34		17		
Gender, Female (%)	10 (29)		8 (47)		0.21
Age	34	68	17	73	0.39

^{2.} For "Patients discharged with: therapy withheld and therapy withdrawn" and "Patients dying in the ICU" percentages represent the total number of patients; For the rest, the percentage represents patients dying in the intensive care unit (ICU).

^{3.} χ^2 test

34	0.15	17	0.21	0.62
9	26	7	29	0.34
9	50	7	67	0.63
8	7.5	7	10	0.30
9	14	7	13	0.96
25		16		
8 (32)		8 (50)		0.25
25	80	16	70.5	0.005
25	0.54	16	1.69	0.11
9	24	12	27	0.08
9	48	12	47.5	0.92
9	6	12	7	0.67
9	8	12	9.5	0.62
117		60		
45 (38)		25 (42)		0.68
117	71	60	71.5	0.68
117	3.1	60	1.7	0.06
117	1.1	60	0.4	0.03
117	3.1	60	1.1	0.02
79	25	35	27	0.05
79	47	35	57	0.02
74	8	35	7	0.80
74	12	35	11	0.15
	9 9 8 9 8 9 25 8 (32) 25 25 9 9 9 117 45 (38) 117 117 79 79 79	9 26 9 50 8 7.5 9 14 25 8 (32) 25 80 25 0.54 9 24 9 48 9 6 9 8 117 45 (38) 117 71 117 3.1 117 1.1 117 3.1 79 25 79 47 74 8	9 26 7 9 50 7 8 7.5 7 9 14 7 25 16 8 (32) 8 (50) 25 80 16 25 0.54 16 9 24 12 9 48 12 9 8 12 9 8 12 117 60 117 71 60 117 3.1 60 117 1.1 60 117 3.1 60 79 25 35 79 47 35 74 8 35	9 26 7 29 9 50 7 67 8 7.5 7 10 9 14 7 13 25 16 8 (50) 25 80 16 70.5 25 0.54 16 1.69 9 24 12 27 9 48 12 47.5 9 8 12 7 9 8 12 9.5 117 60 71.5 117 3.1 60 1.7 117 1.1 60 0.4 117 3.1 60 1.1 79 25 35 27 79 47 35 57 74 8 35 7

¹Data from baseline survey (ref. 19)

age, but the Acute Physiology and Chronic Health Evaluation (APACHE II) and Simplified Acute Physiology Score (SAPS) scores were higher (*Table 2*).

When comparing all patients who died in the ICU in the two periods, there were no significant differences with respect to reasons for admission (p=0.15), number of chronic diseases (p=0.91), or number of organs affected (p=0.19). There was a significant difference regarding the speciali-

ties from which the patients were admitted (p=0.002), mainly due to an increase in the number of medical patients (from 32% to 56%) and a decrease in the number of surgical patients (from 30% to 22%). For patients with therapy withdrawn, the same characteristics were observed.

Questionnaire survey. The response rate was 81% (229/281): 84% (103/122) for nurses, 81% (35/43) for intensivists, and 78% (91/116) for primary physicians.

²Different n due to severity scores being measured at different times, excluding patients admitted < 24 h and patients < 18 years of age

 $^{^{3}\}chi^{2}$ test for "Gender;" otherwise, Mann-Whitney U test as most of the data were not normally distributed

⁴Acute Physiology and Chronic Health Evaluation. Measured once 24 hours after admission

⁵Simplified Acute Physiology Score. Measured once 24 hours after admission

 $^{^6}$ Sepsis-Related Organ Failure Score. Measured daily after the first 24 hours. 1: First measurement 2: Highest Measurement

⁷Time from admission to first consideration on level of therapy

⁸Time from admission to withdrawal decision

ICU = intensive care unit

 Table 3 - Background characteristics: A) Nurses, intensivists, and primary physicians who responded both at base line and after implementation of guidelines (data from post-intervention time); B) All nurses, intensivists, and primary physicians who responded either at baseline or after implementation of guideline.

	N	urses	Inten	sivists	Primary	y physicians	
		n¹ %		n¹ %		n¹ %	\mathbf{p}^2
A. Nurses, inter	isivists, and p	primary physicia	ans who respond	led twice (post-i	ntervention)	
Gender		77		24		51	
Female		75 (97)		10 (42)		18 (35)	< 0.001
Age							
< 40 years		25 (32)		2 (8)		9 (18)	
≥40		52 (68)		22 (92)		41 (82)	0.03
Experience. Current ICU/W	ard (
>0 - < 2 years		0 (0)		2 (8)		5 (10)	0.40
≥2 - < 5 years		24 (31)		6 (25)		15 (30)	
≥5		53 (69)		16 (67)		30 (60)	
Experience. Pro	evious ICU						
None		41 (55)		0 (0)			< 0.001
>0 - < 2 years		12 (16)		0 (0)			
≥2 - < 5 years		6 (8)		1 (4)			
≥5		15 (20)		23 (96)			
B. All responder	nts. At baseli	ne and post-inter	vention				
	Baseline ³	Post- intervention	Baseline ³	Post- intervention	Baseline ³	Post- intervention	
	n¹ (%)	n ¹ (%)					
Gender	112	103	39	35	122	91	
Female	107 (96)	101 (98)	16 (41)	13 (37)	50 (41)	35 (39)	
Age							
< 40 years	50 (45)	41 (40)	14 (36)	8 (23)	59 (49)	34 (38)	
≥40	60 (55)	62 (60)	25 (64)	27 (77)	62 (51)	56 (62)	
Experience. Current ICU/W	ard						
>0 - < 2 years	24 (22)	8 (8)	18 (46)	11 (31)	61 (50)	35 (39)	
≥2 - < 5 years	30 (27)	37 (36)	7 (18)	7 (20)	36 (30)	19 (21)	
≥5	57 (51)	58 (56)	14 (36)	17 (49)	24 (20)	36 (40)	
Experience. Pro	1						
None	68 (61)	53 (53)	3 (8)	3 (9)			
>0 - < 2 years	15 (14)	15 (15)	3 (8)	1 (3)			
≥2 - < 5 years	12 (11)	7 (7)	5 (13)	2 (6)			
≥5	16 (14)	24 (24)	28 (72)	29 (83)			

¹Different n due to missing data

² χ 2 test (gender/age), Kruskal-Wallis (experience, current ICU), Mann-Whitney U test (experience, previous ICU) ³Data from baseline survey (ref. 20)

ICU = intensive care unit

At baseline, the response rate was 88% (273/310) (17). Of the participants, 66% (152/229) responded both at baseline and after the intervention (75% of the nurses, 69% of the intensivists, and 56% of the primary physicians). *Table 3* presents data from all survey responders, but statistical analyses were only conducted for those who responded twice. For participants who responded twice, there was a significant difference between nurses, intensivists, and primary physicians regarding gender, age and previous experience. The same tendency was found for all responders.

Of the participants, 62% (141/229) had read all or part of the guidelines (76% of the nurses, 83% of the intensivists, and 37% of the primary physicians). In the 6 month period, 62% of the participants were involved in end-of-life decision-making and 38% of these had used the guidelines in connection with the decision-making. Of the participants who had used the guidelines, 65% and 31% considered the guidelines usable to a high/very high extent and some extent, respectively.

With respect to satisfaction with end-of-life decision-making, 41% of the participants considered interdisciplinary collaboration very or extremely satisfactory at baseline compared to 48% of the participants after implementation (paired analysis) (*Table 4*). For participants who responded twice, no changes were found in experiences of withholding or withdrawing decisions being changed or unnecessarily postponed (*Table 4*).

At baseline, 55% of the nurses stated that they very often or always were involved in end-of-life decision-making, and 54% of the intensivists and 39% of the primary physicians stated that nurses very often or always were involved (20). After implementation of the guidelines, 41% of nurses, 74% of intensivists, and 52% of primary physicians stated that nurses were very of-

ten or always involved in the decision-making process.

At baseline, 27% of the participants who responded both at baseline and at post-intervention found the quality of care for patients with therapy withdrawn extremely satisfactory; this was the case for 42% post-intervention (p = 0.007). In regard to the quality of care for the patients' relatives this was the case for 23% and 44%, respectively (p = < 0.001).

DISCUSSION

For patients with therapy withdrawn, the median time from admission to first consideration on level of therapy and the median time from admission to a withdrawal decision decreased significantly between baseline and after implementation of the guidelines. No increase in number of patients having therapy withdrawn was found. The study thus suggests that working with guidelines for withholding and withdrawing therapy in the ICU may improve patient care through faster end-of-life decision-making for patients who will not survive intensive care.

Only a small, non-significant increase was found in satisfaction with the interdisciplinary collaboration with end-of-life decision-making. The small increase may be influenced by the fact that at baseline more than 80% of nurses, intensivists, and primary physicians already considered collaboration regarding end-of-life decision-making satisfactory, very satisfactory, or extremely satisfactory (20).

As stated in the guidelines, all relevant healthcare professionals, including nurses, should be part of the decision-making process. However, the percentage of nurses who experienced that they were involved in the decision-making process did not increase from baseline to after implementa-

Table 4 - Nurses', intensivists', and primary physicians' experiences of different aspects of end- of-life decision-making (A. Participants who responded twice and B. All participants).

	_	Nurses	Int	Intensivists	Primar	Primary physicians		Total	
	Baseline ¹	Post- intervention ²							
	n³ (%)	n ³ (%)	n³ (%)	n ³ (%)	n³ (%)	n³ (%)	n³ (%)	n³ (%)	p4
A. Participants who responded twice									
Decisions regarding withholding									
therapy are changed ⁵	63	63	17	17	28	28;	108	108	0.62
Often /very often/always	18 (29)	18 (29)	2 (12)	5 (29)	7 (25)	8 (29)	27 (25)	31 (29)	
Sometimes	38 (60)	37 (59)	9 (53)	9 (53)	10 (36)	12 (43)	57 (53)	58 (54)	
Rarely/never	7 (11)	8 (13)	6 (35)	3 (18)	11 (39)	8 (29)	24 (22)	19 (18)	
Decisions regarding withdrawing									
therapy are unnecessarily postponed	75	75	23	23	38	38	136	136	0.73
Often/very often/always	36 (48)	29 (39)	7 (30)	7 (30)	1 (3)	2 (5)	44 (32)	38 (28)	
Sometimes	30 (40)	43 (57)	14 (61)	14 (61)	12 (32)	15 (39)	56 (41)	72 (53)	
Rarely/never	9 (12)	3 (4)	2 (9)	2 (9)	25 (66)	21 (55)	36 (26)	26 (19)	
General experience of collaboration	92	92	21	21	45	45	142	142	0.19
Very satisfactory/extremely satisfactory	19 (25)	22 (29)	11 (52)	11 (52)	28 (62)	35 (78)	58 (41)	68 (48)	
Satisfactory	41 (54)	36 (47)	7 (33)	10 (48)	15 (33)	10 (22)	63 (44)	56 (39)	
Less satisfactory/unsatisfactory/very unsatisfactory	16 (21)	18 (24)	3 (14)	(0) 0	2 (4)	0 (0)	21 (15)	18 (13)	
B. All participants									
Decisions regarding withholding									
therapy are changed ⁵	94	92	34	29	69	57	197	178	
Often /very often/always	28 (30)	26 (28)	5 (15)	6 (21)	16 (23)	10 (18)	49 (25)	42 (24)	
Sometimes	57 (61)	52 (57)	20 (59)	15 (52)	30 (43)	34 (60)	107 (54)	101 (57)	
Rarely/never	9 (10)	14 (15)	9 (26)	8 (28)	23 (33)	13 (23)	41 (21)	35 (20)	
Decisions regarding withdrawing									
therapy are unnecessarily postponed	109	103	39	33	85	29	233	203	
Often/very often/always	46 (42)	43 (42)	10 (26)	9 (27)	2 (2)	2 (3)	58 (25)	54 (27)	
Sometimes	50 (46)	57 (55)	23 (59)	18 (55)	29 (34)	29 (43)	102 (44)	104 (51)	
Rarely/never	13 (12)	3 (3)	6 (15)	6 (18)	54 (64)	36 (54)	73 (31)	45 (22)	
General experience of collaboration	111	66	38	32	105	82	254	213	
Very satisfactory/extremely satisfactory	27 (24)	29 (29)	16 (42)	13 (41)	(63) 99	59 (72)	109 (43)	101 (47)	
Satisfactory	59 (53)	42 (42)	17 (45)	18 (56)	34 (32)	23 (28)	110 (43)	83 (39)	
Less satisfactory/unsatisfactory/ very unsatisfactory	25 (23)	28 (28)	5 (13)	1 (3)	5 (5)	(0) 0	35 (14)	29 (14)	

baseline with post-intervention data for all participants who responded twice); Sexcluded those who as only reason for changes stated: "Changes in the patient's condition".

tion of the guidelines. This may also be one of the reasons for the small, non-significant increase in satisfaction with the interdisciplinary collaboration, as lack of involvement in decision-making is associated with lower satisfaction (17, 23).

The strengths of this study include development of guidelines based on extensive participation of involved healthcare professionals, a study mix of data from a questionnaire survey and a hospital record review, and high response rates.

Limitations include the time span between baseline and evaluation and a short implementation period. The decrease in time from admission to withdrawal of therapy may be due to implementation of the guidelines, but also to other factors, e.g. to APACHE II and SAPS scores being higher at time of guideline evaluation and to a higher percentage of medical patients. Length of stay is internationally used as an outcome measure for effects of interventions, also in before-after studies (8). However, especially in a beforeafter design the risk of confounders is substantial. The hospital record review on data from 2008 was the first step in the series of projects to examine and improve end-oflife decision-making and care. This entailed the span of 2.5 years between baseline and post-intervention data for hospital record reviews which increases the possibility of other issues than the guidelines having an impact on the changes. The cultural diversity of the individuals involved (patients, family members, and the health care professionals) increases the complexity of end-oflife care (10, 11, 15, 17); issues that are not easily addressed in guidelines. The guidelines were developed and implemented in two ICUs only; this limits the possibility to generalise the results to other ICUs, but the study may be inspirational for other healthcare professionals wanting to improve endof-life decision-making, both within and outside the ICUs.

CONCLUSION

This study indicates that working with guidelines for withholding and withdrawing therapy in the ICU may facilitate improvements in end-of-life decision-making and patient care, but further, multicenter studies are needed to provide more robust evidence.

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