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# The practicalities of terminally ill patients signing their own DNR orders—a study in Taiwan

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## ABSTRACT

**Objectives:** To investigate the current situation of completing the informed consent for do-not-resuscitate (DNR) orders among the competent patients with terminal illness and the ethical dilemmas related to it.

**Participants:** This study enrolled 152 competent patients with terminal cancer, who were involved in the initial consultations for hospice care.

**Analysis:** Comparisons of means, analyses of variance, Student's t test,  $\chi^2$  test and multiple logistic regression models.

**Results:** After the consultations, 117 (77.0%) of the 152 patients provided informed consent for hospice care and DNR orders. These included 21 patients (17.9%) who signed the consent by themselves, and 96 (82.1%) whose consent sheet was signed only by family members. The reasons why patients were not involved in the discussions toward the consent ( $n = 82$ ) included poor physical or psychological condition (44.9%), concerns of the consultant hospice team (37.2%), and the family's refusal (28.2%). On a multivariate analysis, patients' awareness of their poor prognosis (odds ratio = 4.07, 95% confidence interval = 2.05 to 8.07) and their understanding of hospice care (2.27, 1.33 to 3.89) were two independent factors ( $p < 0.01$ ) that influenced their participation in the discussions or their personal signature in the informed consent.

**Conclusion:** The family-oriented culture in Asian countries may violate the principles of the Patient Self-Determination Act and the requirements of the Hospice Care Law in Taiwan, which inevitably poses an ethical dilemma. Earlier truth-telling and continuing education of the public by hospice care workers will be helpful in solving such ethical dilemmas.

Because of the emphasis on the autonomy of patients with terminal illness, the state of California in the USA enacted the Natural Death Act in 1976 to protect patient's rights to establish do-not-resuscitate (DNR) orders and to have a natural death. In 1991, the Patient Self-Determination Act (PSDA) was implemented in the US to ensure that healthcare institutions recognised patients' written advance directives. The PSDA requested patients to be informed of their rights to participate in their medical decision-making and to personally complete written directives in advance.<sup>1</sup>

Given the effect of the PSDA in the US and the development of national hospice programmes in Taiwan, the Hospice Care Law was enacted here in 2000 to respect the will of patients with terminal illness to participate in their medical care and to protect their rights for their end-of-life decisions.<sup>1,2</sup> This law, similar to the Natural Death Act in

California, aims to improve the quality of terminal care. According to the law, terminally ill patients should personally sign informed consent to acknowledge their choice to have hospice care or to establish the DNR order if they are competent.<sup>3</sup> In addition, it requires medical staff to discuss end-of-life care with the patient, and encourages medical teams to make ethical and lawful decisions for terminally ill patients. In enacting this law, Taiwan became the first Asian country to have legislation regarding natural death.

Although the intention of advance directives is good, previous investigators reported that many medical staffs have insufficient understanding of such directives and that there is a low rate of chart documenting of living wills, even after advance directives had been established for many years in the United States.<sup>4,5</sup> Additionally, ethical problems arose when advance directives were promoted and applied in different cultures.<sup>6</sup> In the early stages after the Hospice Care Law was established in Taiwan, many difficulties and ethical dilemmas emerged in clinical practice. One major problem was related to obtaining written informed consent for hospice care or for a DNR order from patients with terminal illness. The purpose of the present study was to explore the current situation of completing this informed consent from competent patients with terminal cancer and to investigate the clinical difficulties or ethical dilemmas related to this issue.

## METHODS

### Study population

We conducted an initial consultation of palliative care with 219 patients with terminal cancer, referred from the emergency department, the outpatient clinic of the hospice, or inpatient wards in a university hospital during January to June 2003. The study excluded those who were not terminally ill, unable to communicate or who had cognitive impairment (eg, coma, confusion, delirium). Finally, a total of 152 patients were enrolled in this study. Patients were classified into two groups according to their participation in decision-making about their lives. Those who participated in the consultation discussions or who personally signed informed consent for DNR were considered to be in the "consensual" group ( $n = 74$ , 48.7%). The other patients, who were not involved in the discussions or end-of-life decision-making, were assigned to the "non-consensual" group ( $n = 78$ , 51.3%). The design of this study and patient selection was approved by the ethical committee in the hospital.

### Data collection

At present, Taiwanese hospice programmes assume that a signed DNR order is a prerequisite for being accepted as a hospice inpatient. Therefore, until they are transferred to the hospice ward, consultant professionals in the hospice care team keep in touch with only those subjects who have signed informed consent forms. The staff of our hospice care team visited patients or their families and discussed with them the informed consent form for hospice care at least once before giving them the form. The patient or family could sign the form at the time of consultation, or they could return it a few days later with or without signing it.

### Instruments

The staff of the hospice care team recorded the consultation form, which included demographic data and patient's physical functions, awareness of their disease status, preparation of after-death affairs, and participation in the consultations. If the patient was absent from the discussions, the consultant team recorded the reasons. Physical functions were evaluated in terms of consciousness, communicative ability, and performance status based on the Eastern Cooperative Oncology Group (ECOG) score. The patient's awareness of their disease was assessed by a score range of 0–3 for items such as "the patient knows the diagnosis", "the patient knows the prognosis", "the patient is aware that death is forthcoming", and "the patient or family understands what hospice care is." The higher the score, the greater the patient's understanding. A "content validity index" was used to determine the validity of the entire form and yielded a content validity index of 0.90. In addition, five senior consultant staff performed a pilot study for three months before the study to confirm the questionnaire's face validity and ease of application.

### Statistical analysis

Data management and statistical analysis were performed by using the statistical software SPSS for Windows V.12.0. Frequency distributions were used to describe the demographic data and the distribution for each variable. The mean and standard deviation (SD) were used to analyse age, ECOG score and degree of disease awareness. We examined differences in demographic data, physical function, and disease awareness between the consensual and non-consensual groups by performing a univariate analysis including the Student's *t* test and  $\chi^2$  test. To identify independent predictors of patients' participation in discussions or providing personal signatures in informed consent, significant factors from the univariate analysis were included in the multivariate analysis if they were judged to be potential confounders. They were tested for significance in the logistic regression model in which being in the consensual group or not was the dependent variable. Calibration of the models was assessed using the Hosmer and Lemeshow Goodness-of-fit test. A *p* value less than 0.05 was considered to be statistically significant in the study.

### Results

The basic characteristics of the 152 terminal cancer patients in the study are summarised in table 1. There were 90 male patients (59.2%) and 62 female patients (40.8%), with a mean age of 61.6 (13.12) years. About half of the 152 patients (48.0%) were older than 65 years, and only three patients were younger than 18 years. With regard to the primary cancer origins in the subject group, liver cancer patients was the largest group

(19.7%), followed by lung cancer patients (17.1%), and colon-rectal cancer patients (12.5%).

Informed consent was signed and retrieved from 117 (77.0%) patients or their families, but only 21 (17.9%) of these consents were signed by patients themselves (table 2). For another 35 (29.9%) patients from the total 117 who participated in the discussions, only their family members signed the consent form. In the remaining 61 (52.1%) patients, family members signed consent without the patients' involvement in the discussions. Among the 35 patients from whom signed informed consent was not given, 17 (48.6%) patients did not participate in the consultations.

The 152 patients enrolled were divided into two groups that we labelled as the "consensual" group and "non-consensual" group. They included 74 (48.7%) and 78 (51.3%) patients respectively (table 2). Among patients who were involved in the discussions, 24.3% signed informed consent themselves. When only family members participated in the consultations, four patients (4.9%) signed the consent personally. Relatives who signed the informed consent were offspring (81.3%), spouses (32.3%), brothers or sisters (8.3%), sons- or daughters-in-law (7.3%), and parents (3.1%).

Reasons why competent patients were not involved in the consultations (*n* = 82) could be categorised into patient, consultant physician, and family factors. Leading reasons were poor physical or psychological condition of the patients (44.9%), concerns of consultant hospice care team (37.2%), and the family's refusal to let the patients participate (28.2%).

Performing univariate analyses for the differences between the consensual and non-consensual groups, the consensual

**Table 1** Demographic characteristics of patients (*n* = 152)

Variable	N (%)
Sex	
Men	90 (59.2)
Women	62 (40.8)
Age (years)*	
< 18	3 (2.0)
19–44	23 (15.1)
45–64	53 (34.9)
≥ 65	73 (48.0)
Education level	
Illiterate	17 (11.2)
Elementary school	45 (29.6)
Junior high school	21 (13.8)
High school	42 (27.6)
College	27 (17.8)
Marital status	
Married	116 (76.3)
Single	17 (11.2)
Widowed	16 (10.5)
Divorced	3 (2.0)
Site of primary tumour	
Liver	30 (19.7)
Lung	26 (17.1)
Colon and rectum	19 (12.5)
Head and neck	12 (7.9)
Stomach	12 (7.9)
Gallbladder	9 (5.9)
Breast	8 (5.3)
Cervix	5 (3.3)
Pancreas	5 (3.3)
Other	26 (17.1)

\*Mean SD = 61.6 (16.2).

**Table 2** Comparison of consensual (n = 74) and non-consensual groups (n = 78)

Discussion and Consent	Consensual group	Non-consensual group
	n (%)	n (%)
Patients have participated the discussion		
Patients signed consent personally	17 (11.2)	0 (0)
Family signed consent only	35 (23.0)	0 (0)
Consent not signed	18 (11.8)	0 (0)
Patient didn't participate the discussion		
Patient signed consent personally	4 (2.6)	0 (0)
Family signed consent only	0 (0)	61 (40.1)
Consent not signed	0 (0)	17 (11.2)
Total	74 (48.7)	78 (51.3)

group was significantly younger (57.5 vs 65.6 years;  $p < 0.01$ ) and had higher educational levels (55.4% vs 35.9% above junior high school,  $p < 0.05$ ) than the non-consensual group. Although ECOG scores were lower in the consensual group than in the other group (2.9 vs 3.3,  $p < 0.05$ ), consciousness ( $p = 0.447$ ) and communicative ability ( $p = 0.077$ ) did not show significant differences. Patients in the consensual group had a better awareness of their disease diagnosis, prognosis, impending death, and understanding of hospice care than did the others ( $p < 0.01$ ). However, death preparation and decisions on the place of death, choice of non-curative therapy, and decisions of DNR were not significantly different in both groups (tables 3 and 4).

**Table 3** Univariate analysis ( $\chi^2$ ) between consensual (n = 74) and non-consensual groups (n = 78)

Variable	Consensual	Non-consensual	$\chi^2$	p Value
	n (%)	n (%)		
Sex			1.9	0.167
men	48 (64.9)	42 (53.8)		
women	26 (35.1)	36 (46.2)		
Marital status			0.3	0.560
married	58 (78.4)	58 (74.4)		
single or widowed	16 (21.6)	20 (25.6)		
Educational level			5.8	0.016*
junior high school or lower	33 (44.6)	50 (64.1)		
high school graduate or higher	41 (55.4)	28 (35.9)		
Consciousness			0.6	0.447
aware	58 (78.4)	57 (73.1)		
lethargic	16 (21.6)	21 (26.9)		
Communicative ability			3.1	0.077
Normal	52 (70.3)	44 (56.4)		
impaired	22 (29.7)	34 (43.6)		
Preparation of after-death affairs			1.5	0.221
yes	18 (24.3)	26 (33.3)		
no or uncertain	56 (75.7)	52 (66.7)		
Decision for the place of death			1.3	0.252
yes	10 (13.5)	16 (20.5)		
no or uncertain	64 (86.5)	62 (79.5)		
Choice for non-curative therapy			1.9	0.167
yes	48 (64.9)	42 (53.8)		
no or uncertain	26 (35.1)	36 (46.2)		
Decision of DNR			3.9	0.048*
yes	59 (79.7)	51 (65.4)		
no or uncertain	15 (20.3)	27 (34.6)		

\*Significant difference ( $p < 0.05$ ).

Results of the logistic regression analysis of the factors correlated with the consensual group, ie, participating in discussions or personally signing informed consent, are shown in table 5. Awareness of their prognosis (OR = 4.07, 95% CI = 2.05 to 8.07) and understanding of hospice care (2.27, 1.33 to 3.89) were two independent predictors of the consensual group. For the fitness of the model, the p value of the Hosmer and Lemeshow Goodness-of-fit test was 0.315.

## DISCUSSION

Taiwan has spent more than six years debating the Hospice Care Law, and also the Natural Death Act, which were established in June 2000, the first in Asia. To our knowledge the present study is one of the first studies to investigate the situation of completing written informed consent and the ethical dilemmas related to it in this context, particularly in the Asia-Pacific region.

Decision-making ability is a fundamental component of informed consent. The Hospice Care Law states that terminally ill patients should personally sign informed consent unless they are unable to express their willingness explicitly.<sup>2</sup> However, whether all the competent patients identified in the study could make decisions or explicitly express their wishes is difficult to determine, and would have required further confirmation. The hospice length of stay in the study was 10.5 (7.9) days, and 60.7% of the patients died in the hospice. Given that cognitive impairment is often prevalent during the last weeks of life,<sup>7</sup> some patients may have been included in the non-consensual group because their physical or psychological status influenced their decision-making ability. Otherwise, when the hospice care team cannot make sure of the patient's capacity, a reliable assessment tool is needed.<sup>8,9</sup>

Previous investigators in Taiwan reported that most medical staff support the regulation that competent patients should sign informed consent themselves.<sup>10</sup> However, we found a high percentage of family members who participated in consultations and signed informed consent instead of competent patients. Our findings revealed the predominance of family in the cultures of Taiwan. However, in our clinical practice, most of the competent patients did not seem opposed to letting their families learn of their medical information first or even to letting their families make medical decisions for them. In Japan, informal entrusting of everything to the family is also highly prevalent.<sup>11</sup> This phenomenon probably reflects values in oriental cultures, in which family is the smallest unit of identity and decision-making. Therefore, end-of-life care for one member cannot be decided outside this fundamental social unit. Patients have the right to pass decision-making authority to their children with the confidence that their loved ones will protect their welfare. The role of sons and daughters in making decisions for their elders is particularly important and regarded as a basic duty.<sup>12-15</sup> This is probably why most representatives who signed informed consent in our study were the patients' offspring.

To respect the patient's autonomy and to prevent the family's opinion from overriding the patient's in family-oriented cultures, signing informed consent in advance or appointing a family member as a healthcare proxy should be highly encouraged. However, even the authorised proxy cannot sign informed consent until the patient is unable to express his or her intent, according to the Hospice Care Law.<sup>2</sup> Hence, the common practice of Asian patients' passing their decision-making rights to their family when they are still competent conflicts with the current regulations.<sup>14</sup> Because medical ethics

**Table 4** Univariate analysis (*t* test) between consensual (n = 74) and non-consensual groups (n = 78)

Variable	Consensual (SD)	Non-consensual (SD)	t	p Value
Age (years)	57.5 (13.9)	65.6 (17.3)	-3.1	0.002**
ECOG score	2.9 (0.9)	3.3 (0.8)	-2.5	0.013*
Awareness of disease diagnosis	2.8 (0.5)	2.3 (1.0)	4.6	0.000**
Awareness of disease prognosis	2.6 (0.5)	1.9 (0.8)	6.5	0.000**
Awareness of near-dying	1.4 (0.6)	1.1 (0.7)	2.9	0.005**
Patients' understanding of hospice care	1.0 (0.8)	0.3 (0.6)	5.7	0.000**
Families' understanding of hospice care	1.4 (0.8)	1.5 (0.7)	-1.0	0.317

\*  $p < 0.05$ , \*\*  $p < 0.01$ ; ECOG, Eastern Cooperative Oncology Group.

should not be against traditional cultural values, revising the law to allow a surrogate to make medical decisions under the supervision of competent patients deserves consideration.

Kamer *et al* reported that legislation substantially changed the frequency of documentations of DNR orders (from 22% to 93%); however, it appeared to have no meaningful effect on the patient's opportunity to participate in discussions about CPR (change from 13% to 16%).<sup>15</sup> In our study, though a high percentage of informed consent forms were signed after hospice consultations, only a few were signed by patients involved in the consultations. Therefore, hospice care teams should appreciate the fact that a single consent form with patient or family signatures should never be viewed as adequate fulfilment of the informed consent duty.<sup>16</sup> Continuing communication could be the key to informed consent.

Truth telling is also an important principle to account for.<sup>12</sup> In the US, truth telling is considered a basic responsibility of clinicians.<sup>17</sup> However, in Taiwan, this is one of the most common medical dilemmas for caregivers in hospices.<sup>18</sup> Our study showed that patients who were better informed of their prognosis or about hospice care were most likely to play an active role in their own end-of-life care. A previous report showed that such disclosure promoted patients' participation in healthcare decisions and that it was good for relationships between patients and their physicians.<sup>19</sup> Although disclosure is considered essential to good clinical care and is supported by laws requiring informed consent, disclosure should also take account of the patients' cultural and religious beliefs. For example, Asian cultures view blunt, but truthful, communication as extremely rude and disrespectful or even harmful.<sup>20</sup> Some believe that protecting patients from the truth and making decisions for them is a way of relieving the patients' burden.<sup>6</sup> The difficulty of truth telling is probably the reason why some families refused to allow the patient to participate in such discussions in our study.

Miller reported that many hospice programmes usually assume that a patient who wishes to be resuscitated is not an

**Table 5** Logistic regression of factors independently correlated with the consensual group

Variable	$\beta$	Standard Error	Odds Ratio (95% Confidence Interval)
Awareness of disease prognosis	1.40	0.35	4.07 (2.05 to 8.07*)
Patients' understanding of hospice care	0.82	0.27	2.27 (1.33 to 3.89*)

Note: adjusted for age, education, Eastern Cooperative Oncology Group score, decision for a DNR order, awareness of disease diagnosis, and awareness of near-dying. Hosmer and Lemeshow goodness-of-fit test,  $p = 0.315$ .  $\beta$  = Normalised beta coefficient. \* $p < 0.01$

appropriate candidate for hospice care.<sup>21</sup> In Taiwan, our programmes also assume that a signed DNR order is a prerequisite for being accepted as a hospice inpatient. For patients who are unaware of their prognosis or diagnosis of terminal illness, family members signed informed consent probably because they wanted the patients to be admitted and to receive palliative care as soon as possible. Some flexible programmes in the United States accept patients into the hospice ward if they agree with the hospice principles, even if they have not yet signed a DNR order.<sup>21</sup> This approach allows patients to accept their terminal status and to manage their end-of-life care step by step. Such programmes do not expect patients to fully understand or recognise hospice care before receiving palliative care. Hence, a previous study revealed that only 40% of all patients in palliative care consultations were recommended to document their advance directives.<sup>22</sup>

In our study, family members sometimes participated in consultations instead of patients because of concerns of the consultant hospice care team. These medical staff might have had points of view similar to those mentioned above. A hospice that fails to involve family members or that admits a patient without family consent jeopardises patient care and takes a considerable legal risk.<sup>16</sup>

The findings from this study should be interpreted with caution because of several limitations. First, the study only applies to a hospital population; the generalisability of the results should be measured. Yet, there is similar demographic data of patients and dilemmas related to this issue among hospices in Taiwan, according to previous reports.<sup>23</sup> Therefore, selection bias is likely to be minimal in this study. However, further work with multi-centre studies would still be worthwhile. Secondly, the patients were divided into two groups based on the consensus, which may have different cultural considerations.

In conclusion, the family-oriented culture in Asian countries may make it easy to violate the principles of the Patient Self-Determination Act and the current requests of the Hospice Care Law in Taiwan. Earlier truth-telling and comprehensive education of hospice care for the public will be helpful in solving these ethical dilemmas.

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