Explaining the Process of Determining Futility Increases Lay Public Acceptance

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Abstract

Rationale: National guidelines have laid out a process to conflict resolution in cases of potentially inappropriate medical interventions.

Objectives: To determine the association between information about a process-based approach and lay public perceptions of the appropriateness of withholding medically inappropriate interventions.

Methods: Respondents from a nationwide sample completed a survey with two adult intensive care unit–based vignettes: one about advanced cancer where doctors told the family that additional chemotherapy would not be offered, and a second case of multiorgan failure after brain hemorrhage where dialysis would not be offered. Participants were randomly assigned to see or not see information about a detailed process for the determination to withhold (second opinion, ethics consultation, exploring transfer to another institution). The primary outcome was the perceived appropriateness of not providing the treatment (four-point scale, dichotomized for analysis, modified Poisson regression), and the secondary outcome was the negative emotional reaction to the case

(positive and negative affect schedule, range 1–5, higher is greater negative emotional response, linear regression).

Results: A total of 1,191 respondents were included. Providing detailed process information increased the perceived appropriateness of withholding treatment by approximately 10 percentage points in each vignette: (chemotherapy, 75.7–85.4%; dialysis, 68.0–79.3%). Process information remained associated with perceived appropriateness of withholding treatment after adjustment for order effects and prespecified respondent characteristics (chemotherapy: prevalence ratio, 1.13; 95% confidence interval [CI], 1.07–1.19) (dialysis: prevalence ratio, 1.17; 95% CI, 1.10–1.25). Process information was not associated with emotional response to the cases (chemotherapy: $\beta = -0.04$; 95% CI, -0.16 to 0.09) (dialysis: $\beta = -0.02$; 95% CI, -0.14 to 0.10 ; both adjusted for order effects).

Conclusions: Providing process-based conflict resolution information increased public acceptance of determinations of medical futility, supporting the practice outlined in national consensus statements.

Keywords: medical futility; ethics committees; withholding treatment

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Cases of potentially inappropriate or medically futile interventions for certain patients, such as Charlie Gard (1) and Baby K (2), have garnered great public attention.

They highlight the potential conflict between the opinions of the lay public and healthcare providers around providing life-sustaining but medically futile or potentially

inappropriate interventions. With the advent of new life-sustaining, resource-intensive interventions, the problem of providing surrogate-requested but

potentially medically inappropriate interventions has become a pressing concern in the field of bioethics and critical care (3). Specifically, it remains unclear what options families may have when they disagree with the medical team (4).

In recent years, a process-based approach to resolving disputes around determinations of medical futility has become increasingly adopted by ethicists and medical institutions. This has arisen following the creation of an international position statement by multiple critical care groups on responding to requests by surrogate decision makers for potentially futile interventions (5, 6). This process typically involves a second opinion from an independent physician, ethics consultation and review by an ethics committee, and investigating the possibility of transfer to another institution before a final determination on withholding or withdrawing interventions is made. There is a paucity of data on lay public opinion of this process-based approach to medical futility and whether this process is associated with an increased acceptance of the appropriateness of futility determinations and subsequent decisions to limit interventions. Given differences in how the nonmedical public interprets physician's predictions of futility (7), it is possible that public opinion may vary substantially from the current ethical consensus. Therefore, understanding whether the use of process-based mechanisms to determine medical futility actually impacts public opinions on withdrawing or withholding treatment is important.

We conducted a vignette-based survey of members of the general public to assess whether providing information about a process-based approach to conflict resolution affected the perceived appropriateness of decisions to withhold medical interventions determined to be medically nonbeneficial. We hypothesized that the inclusion of process information would increase respondents' rating of the appropriateness of the medical team's decision to withhold an intervention. As a secondary aim, we sought to determine whether inclusion of process information would reduce respondent's negative emotional response to withholding interventions.

Methods

Respondent Population

Respondents were recruited through Survey Sampling International, a private survey

company. A nationwide sample from the United States was recruited with the following proportional quota goals to attempt to match the general demographics of the U.S. adult population: equal sex; one-third of respondents younger than the age of 40, one-third between 40 and 65, and one-third older than the age of 65; and approximately 14% African-American respondents, 14% Hispanic respondents, and 4% other/multiracial respondents. Although this approach ensured diversity in the sample, it is not a representative random probabilistic sample of the U.S. population. Survey Sampling International provided participants with a modest incentive for completion that varied by respondent per their standard protocol. Participants were eligible for inclusion in the analysis if they answered all primary and secondary outcome questions and did not indicate that they were currently employed as a physician, nurse, physician assistant, or nurse practitioner.

Survey Design

We created an online vignette-based survey where respondents read two hypothetical clinical scenarios from the perspective of an uninvolved third party. This perspective was selected to allow for more objective assessment of both prognostic information, especially in the context of neurologic injury (8), and action on the parts of the physicians and the family members discussed in the vignette. Although the definition of medical "futility" and the appropriate terminology remains a point of contention (9), we used the definition of "potentially inappropriate" laid out in the American Thoracic Society position statement (5) in designing our survey.

Two vignettes describing a critically ill adult in an intensive care unit were presented in a randomized order. One vignette ("chemotherapy vignette") detailed a situation in which the medical team and a patient's daughter were discussing providing chemotherapy to a patient with metastatic cancer in which the medical team believed that the chemotherapy would be of no benefit. The other vignette ("dialysis vignette") detailed a situation in which the medical team and a patient's daughter were discussing providing emergent dialysis for a patient with a devastating intracerebral hemorrhage in which the medical team believed that the risks and harms of dialysis outweighed the benefits. In both vignettes,

the medical team's concerns and the patient's daughter's concerns were outlined.

Each respondent was randomized to either see or not see process information for both cases to eliminate contamination effects. "Process information" describes processes outlined in national position statements on resolving questions of nonbeneficial interventions (5), including a second opinion from an independent physician, review of the case by a hospital ethics committee, and exploration of the option of transferring the patient to another institution (Table 1). Randomization was done within the online survey software (Qualtrics) by randomly assigning a 0 or 1 value for process information and case order for each participant, then displaying the appropriate vignette text based on the assigned randomization. Both vignettes concluded with the medical team ultimately deciding to withhold the intervention in question. Although withholding and withdrawing are considered ethically equivalent (10), the emotions associated with these decisions can be separate, and so we wanted to focus on withholding specifically. The full text of the vignettes is available in the online supplement. A preliminary version of the survey was pilot tested with 12 respondents recruited from a university health research volunteer website targeting the general public. These pilot respondents completed cognitive interviews with a study team member to assess clarity of wording of the vignettes and questions. Minor wording clarifications were made based on the cognitive interviews.

Primary and Secondary Outcome Question

The primary outcome was the question: "How appropriate do you find the decisions made by the doctors"? Respondents rated appropriateness on a four-point Likert-type scale with options of "completely inappropriate," "slightly inappropriate," "slightly appropriate," and "completely appropriate." Our prespecified analysis plan was to dichotomize responses as acceptable or unacceptable for all analyses for ease of interpretation (11).

The secondary outcome assessed negative emotional response to the vignette. We used a modified version of the short form of the Positive and Negative Affect Schedule (12) with five selected negative elements chosen for brevity. Respondents were asked "Indicate the extent to which you

Table 1. Overview of case vignettes

Element of case	Chemotherapy Vignette	Dialysis Vignette
Patient characteristics	Older man with advanced metastatic cancer Previously responded to chemotherapy, but cancer is progressing despite treatment Admitted to intensive care unit for 1 wk Has pneumonia and is on a ventilator Unconscious, unable to get out of bed on his own, and unable to make medical decisions	Older man admitted 1 wk ago for brain hemorrhage Underwent initial emergency brain surgery but not improving Has an infection, low blood pressure, and failing kidneys Unable to move or control bodily functions, cannot communicate or make medical decisions
Process information*	<p>“The doctors have gotten a second opinion on the case from other experts, who agree that the risks of [chemotherapy/dialysis] are too great. The doctors have also discussed the case with the hospital ethics committee. The ethics committee is a group of experts including doctors, nurses, social workers, lawyers, philosophers, and community members. Members of the ethics committee review the case. They say that if the treating doctors think the treatment would do more harm than good, the doctors do not have to provide that treatment. After the recommendation by the hospital ethics committee, the man’s doctors call several other hospitals to see if they would be willing to accept the patient for transfer to consider treatment, and all other hospitals decline.</p> <p>The doctors explain to the daughter that they have gotten a second opinion, talked to the ethics committee, and talked to other hospitals.”</p>	

*Process information was randomly shown to half of respondents. Other than referring to chemotherapy or dialysis, this process information was identical for both vignettes.

feel each emotion after reading this story,” with options of distressed, upset, hostile, ashamed, and afraid assessed on a five-point scale from 1 = “very slightly or not at all” to 5 = “extremely.” An overall negative emotional response score was created for each case by taking the mean of the five individual emotion items.

Respondent Characteristics and Attitudes

The survey concluded with a set of descriptive demographic questions, including: prior experience as a surrogate decision maker, presence of an advance directive, recent contact with the medical system, personal or familial exposure to chemotherapy or dialysis, a validated scale for trust in physicians (13), a validated question to assess health literacy (14), level of education, current employment as a physician or nurse, age, political affiliation (15), sex, race-ethnicity, and religiosity (16). Because of a transcription error, one item was inadvertently omitted from the trust in physician’s scale. To assess general attitudes about importance of quality of life versus length of life respondents were asked which of the following statements they most agreed with: “Quality of life is the most important thing,” “Quality of life is more important but length of life matters,” “Length of life is more important but quality of life matters,” and “Length of life is the most important thing,” based on a previously used question (17). A full list of the primary, secondary, and demographic questions is available in the online supplement.

Statistical Analysis

Descriptive statistics for participant characteristics were calculated overall and by whether process information was shown. Modified Poisson regression as described by Zou (18) was used to assess the association of process and other predictors with the participants’ impression of appropriateness, with separate regression models estimated for each vignette. This technique allows for direct estimation of prevalence ratios rather than odds ratios, which is more appropriate for highly prevalent outcomes (18). The target sample size was estimated based on a two-sample comparison of proportions for the primary outcome measure, assuming a control group proportion of 0.5, effect size of 0.1, 90% power, and α of 0.05. With these parameters, the target sample size was estimated at 1,038, which we inflated slightly to a goal of 1,200 to allow for possible missing data. The primary outcome for each case was assessed with a model including the process variable and case order as covariates. To investigate whether the effects were robust, a fully adjusted model for each vignette was estimated adding the following prespecified potential confounders: age (linear per age category), sex (female vs. male/transgender/other), race-ethnicity (black, Hispanic of any race, other, or white), education (Bachelor’s degree or higher, some college or Associate’s degree, or high school or less), trust in medical profession scale (linear scale ranging from 1 to 5, higher score is higher trust), attitude

that length of life is more important than quality of life (dichotomized from four-point scale), prior experience as a surrogate decision maker, health literacy (linear), political affiliation (linear, seven-point scale ranging from -3 = strong democrat to $+3$ = strong republican), religiosity (linear seven-point scale), presence of personal advance directive, whether they had seen a doctor or been hospitalized in the prior 6 months, personal or family history of chemotherapy for cancer, and personal or family history of dialysis. Because of the limited power to investigate effect modification, there were no interaction terms included in the fully adjusted model. To assess the secondary outcome of the association between process information and the participant’s emotional reaction to each vignette, linear regression models predicting the mean Positive and Negative Affect Schedule score with process and case order as predictors were estimated.

Institutional Review Board Approval

This project was approved as exempt from full review by the University of Michigan Institutional Review Board based on minimal risk to adult subjects with an anonymous survey (HUM00139452).

Results

A total of 1,361 individuals opened the survey, and 1,311 (96.6%) agreed to

continue after reading the consent page. Of these 1,311, a total of 1,191 (90.8%) were eligible for inclusion in the analysis based on answering the primary and secondary outcome questions and not working as a clinician. Respondent demographics overall and by presence or absence of process information are reported in Table 2.

For the chemotherapy vignette, 959 of the 1,191 respondents (80.5%) rated the decision to withhold chemotherapy as appropriate (Table 3). For the dialysis vignette, 877 of the 1,191 respondents (73.6%) rated the decision to withhold dialysis as appropriate. For each vignette, providing process information was associated with about a 10% absolute increase in the proportion of respondents who believed that withholding the treatment was appropriate.

Results from the regression models for the association between process information and perceived appropriateness for each case vignette are shown in Table 3. For both vignettes, the inclusion of process information was associated with respondents being more likely to consider withholding the intervention to be appropriate. This association between process information and perceived appropriateness persisted when adjusting for case order and in the fully adjusted model accounting for prespecified potential confounders (Table 3). Additional details from the fully-adjusted model are shown in Table E1 in the online supplement.

For the secondary outcome of negative emotional response (Positive and Negative Affect Schedule), the mean negative affect score was 2.3 for the chemotherapy vignette, and 2.4 for the dialysis vignette, indicating that the overall negative emotional response to the cases was between “2 = little” and “3 = moderately.” Providing process information had no association with participant negative emotional response for either the chemotherapy case ($\beta = -0.04$; 95% confidence interval, -0.16 to 0.09 ; $P = 0.57$) or dialysis case ($\beta = -0.02$; 95% confidence interval, -0.14 to 0.10 ; $P = 0.73$), adjusting for case order.

Discussion

We found that members of the lay public were more likely to find a decision to

Table 2. Participant characteristics and attitudes

Characteristic	Overall % or Mean (SD) (n = 1,191)	Process Information Absent % or Mean (SD) (n = 597)	Process Information Present % or Mean (SD) (n = 594)
Age*			
18–24	4.8	4.9	4.7
25–34	20.2	18.9	21.4
35–44	18.7	20.3	17.2
45–54	19.3	20.1	18.6
55–64	18.7	19.1	18.4
65–74	15.0	13.9	16.0
75 and older	3.3	2.9	3.7
Female†	49.9	51.5	48.2
Race-ethnicity†			
Non-Hispanic white	74.0	75.7	72.3
Black	10.4	8.6	12.3
Hispanic, any race	8.2	8.9	7.4
Other/multiracial/refused	7.4	6.9	7.9
Education†			
High school or less	23.3	25.3	21.3
Associate's/some college/trade school	36.0	35.4	36.6
Bachelor's or higher	40.7	39.3	42.2
Prior experience as surrogate‡	36.7	36.0	37.4
Mean religiosity‡§	4.0 (2.1)	4.0 (2.1)	3.9 (2.1)
Quality vs. length of life*			
Quality most important	49.1	50.3	47.9
Quality more important but length matters	42.1	42.2	42.0
Length more important but quality matters	7.4	5.9	8.9
Length most important	1.4	1.7	1.2
Mean rating of trust in physicians*	3.0 (0.9)	3.0 (0.9)	3.0 (0.8)
Seen a doctor or hospitalized in past 6 mo*	47.7	45.4	49.9

Definition of abbreviation: SD = standard deviation.

*Missing 1 data point.

†Missing 2 data points.

‡Missing 3 data points.

§Religiosity measured on a scale of 1 (not religious at all) to 7 (very religious).

|| Trust measured based on scale from 1 (low trust) to 5 (high trust); one item from original scale omitted.

withhold a medically futile intervention appropriate if they were provided information about a process-based conflict resolution mechanism. However, exposure to this process information did not affect respondents' negative emotional response to these vignettes. Although there was an overall broad agreement that the decision made by the medical team in both vignettes was appropriate, a notable minority of participants found each decision inappropriate.

There are several potential explanations for the increase in appropriateness driven by the presence of process information. Respondents may feel that when they see a medical team go through a more formal process, they have greater trust in their prognostication and medical recommendation (19), because they may now believe it reflects a

broader consensus by multiple professionals rather than by a single provider. Respondents may also believe that a formal process allows for the family's voice to be part of the decision-making process (20, 21), whereas a single medical team or provider deciding to withhold does not allow for this.

Although inclusion of process information did increase respondent's appropriateness ratings, it did not change their negative emotional reaction to the cases. Given that respondents were members of the general public shown hypothetical vignettes and asked to take a third person perspective, there may not have been a strong emotional connection to begin with. This hypothesis is supported by the relatively low baseline ratings for negative emotional reaction to each case. The

Table 3. Associations of process information with perceived appropriateness of withholding treatment

	Overall	Process Information Absent	Process Information Present	P Value
Number of participants	1,191	597	594	
Chemotherapy vignette				
N (%) rating decision appropriate*	959 (80.5)	452 (75.7)	507 (85.4)	
Unadjusted prevalence ratio (95% CI)		Ref	1.13 (1.07–1.19)	<0.001
Order-adjusted prevalence ratio (95% CI) [†]		Ref	1.12 (1.06–1.18)	<0.001
Fully adjusted prevalence ratio (95% CI) [‡]		Ref	1.13 (1.07–1.19)	<0.001
Dialysis vignette				
N (%) rating decision appropriate*	877 (73.6)	406 (68.0)	471 (79.3)	<0.001
Unadjusted prevalence ratio (95% CI)		Ref	1.17 (1.09–1.25)	<0.001
Order-adjusted prevalence ratio (95% CI) [†]		Ref	1.16 (1.08–1.24)	<0.001
Fully adjusted prevalence ratio [‡]		Ref	1.17 (1.10–1.25)	<0.001

Definition of abbreviations: CI = confidence interval; Ref = reference.

All relative risks were estimated with modified Poisson regression models.

*Responses on appropriateness were dichotomized from four-point scale (completely inappropriate to completely appropriate).

[†]Includes process information and vignette order as covariates.

[‡]Fully adjusted models include process information, vignette order, age, sex, race-ethnicity, education, prior experience as surrogate, health literacy, political affiliation, religiosity, trust in physicians, attitudes about length versus quality of life, presence of advance directive, recent contact with medical system, prior experience with chemotherapy, and prior experience with dialysis. *n* = 1,186 for these models because of missing data on certain covariates.

negative emotions may also have been associated with the overall tragedy of the situation rather than the decision to withhold the intervention specifically. We do not know if there would be similarly high rates of perceived appropriateness or similar association with process information if this study had been done in actual surrogates of critically ill patients. However, more than 35% of our sample had prior experience as a surrogate decision maker. Future studies to identify whether these findings can be

replicated in a population of surrogate decisions makers for individuals currently in an intensive care unit are warranted.

Our findings suggest that the fair process approach outlined in multiple national society position statements (5, 6) should be encouraged to help increase the satisfaction of the general public with futility determinations. In addition to adoption at the institutional level, individual clinicians involved in the

process of a futility or potentially inappropriate intervention determination should consider disclosing the process to patients and family members. Finally, to build trust in the medical system and to help shape public policy, the benefits of this fair process approach should be used in public education and public discourse.

Limitations

Using hypothetical vignettes may limit the applicability to actual clinical care, although this design allowed us to experimentally manipulate the detailed process information and recruit participants in an efficient manner. We used a U.S.-based, demographically diverse but not necessarily representative sample. This may exclude point of view of other nations and cultures and may not fully capture the view of the public in the United States. We also did not have data on geography and were unable to explore any geographic differences in responses or attitudes surrounding potentially futile treatment (22, 23). Finally, this is a work of descriptive empirical ethics, and as such we are not attempting to introduce a definition of futility or outline the ethical underpinnings of a process-based approach.

Conclusions

Informing surrogates of a process-based approach to determining medical futility increased public acceptability. Intensive care unit personnel should consider explicitly providing detailed information to surrogates on the processes involved in determinations of medical futility. ■

Author disclosures are available with the text of this article at www.atsjournals.org.

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