Author's response to reviews

Title: To Evaluate the Effectiveness of Health Care Ethics Consultation Based on the Goals of Health Care Ethics Consultation: A Prospective Cohort Study with Randomization

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Dear Editor, BMC Medical Ethics

We are pleased to submit our revised manuscript entitled: “To Evaluate the Effectiveness of Health Care Ethics Consultation Based on the Goals of Health Care Ethics Consultation: A Prospective Cohort Study with Randomization”, for consideration as a research article. We thank editors’ and reviewers’ for their comments and suggestions on the prior version of the manuscript.

In this version of the manuscript, we have done a lot of work to revise our manuscript following the three reviewers’ comments and suggestions. We also provided a point-to-point response to each reviewer in the following pages.

This revised manuscript has not been previously published and is not under consideration in the same or substantially similar form in any other journals. All authors listed in this revised manuscript have contributed substantially to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; (3) final approval of the version to be submitted. The authors have no competing interests.

Best Regards,

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To Referee 1, Dr. Tobin
Dear Dr. Tobin,

Thank you for your thoughtful comments on our work. Our point-to-point responses to your comments are as follows:

<Major Compulsory Revision>

1. This study was approved by the Research Ethics Committee in National Taiwan University Hospital. We added this information at the end of the “Statistical Analysis” sub-section (highlighted by yellow). In this study, we did not deny any request for HCEC from the health care team members. Please check Figure 1. If the patient was randomly assigned to the UC group, the patient and the health care team for the most part did not receive HCEC. The UC patients still received the medical care which considered appropriate to the patient, e.g. social worker consultation, cardiologist consultation. However, the health care team members of four cases, though belonging to the UC group, did both request and receive HCEC (please check the right arm of Figure 1). We did not decline any requests for HCEC made by health care team members even if the case was initially assigned to the UC group. In comparison, two of the 33 cases which were assigned to the HCEC group did not have HCEC performed because the attending physicians of the two cases declined HCEC, which was honored. Informed consent was done and oral consent was obtained in this study.
2. We addressed the patient's random assignment to the HCEC group or UC group in the “Study Design” sub-section. In the “Intention-to-treat Principle” sub-section, we stated “if a patient with medical uncertainty or conflict regarding value-laden issues was randomly assigned to the HCEC group, but ultimately did not receive HCEC service, the patient was still retained in the HCEC group when the data were analyzed.” Please kindly let us know if anything additional information is necessary to be added on.

3. Thank you for pointing out this important issue. The survival rate at hospital discharge was not different between the two groups (HCEC 21.21%, UC 27.59%, \( p = 0.56 \)), but certainly the length of survival was different between the two groups (Please check the “Outcome Data” in Table 2). We corrected this in the “Results” of “Abstract” (highlighted by yellow), and the “Main Findings” sub-section in the “Results and Discussion” (highlighted by yellow).

4. Thank you for your kind reminder about the ambiguity of how consensus was reached. “Any of the morally acceptable options suggested by the ethics consultant was followed” is solely for the HCEC group. We added the following in the “Data Collection” sub-section under “Methods” section (highlighted by yellow) to clarify the ambiguity: “A consensus regarding the goal of medical care was achieved in the HCEC group if any of the morally acceptable options suggested by the individual ethics consultant was followed, and in the UC group if patients/family members and health care team members agreed on any options for the goal of medical care. Health care team members were contacted about whether there was a consensus on the goal of medical care after the onset
of medical uncertainty or conflict regarding value-laden issues in the UC group, or after the HCEC was done in the HCEC group.” We did not interview any of the patients/family members and health care team members. We contacted health care team members (usually the nurse in charge of the patient, head nurse, or the primary care resident) and asked them if there is a consensus on the goal of medical care between patients/family members and health care team.

5. Please see the following tables (Example Table 1 and Example Table 2). We showed the breakdown of reasons by groups. In Example Table 1, we cannot test the statistical significance using the Chi-squared test because of the insufficient sample size (insufficient degree of freedom). We then collapsed the issues of Individual autonomy/Family autonomy, Treatment Refusal, Legal issues, Complementary and Alternative Medicine, Hospice/Palliative Care, Negligence, Euthanasia, and Surrogacy to “Others”. Please see Example Table 2, after testing the distribution using the Chi-squared test, it seems that the issues of initiating ECMO is not a confounder ($p = .113$). However, we cannot add this to Table 2 in our manuscript. In Table 2, the column of HCEC and UC showed the sample size of HCEC and UC, respectively. That is, each variable of HCEC is exactly equal to the sample size of HCEC ($n = 33$), and each variable of UC is exactly equal to the sample size of UC ($n = 29$). The overall issues of the 33 HCEC patients were 69, and the overall issues of the 29 UC patients were 57. We decided to add the average number of ethical issues in Table 2 (highlighted by yellow), instead of adding Example Table 2 to Table 2 in our manuscript. Please let us know if you have any other concerns.
## Example Table 1

<table>
<thead>
<tr>
<th>Issues</th>
<th>HCEC</th>
<th>UC</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagreement between health care team and family members</td>
<td>22</td>
<td>15</td>
<td>37 (59.68%)</td>
</tr>
<tr>
<td>Withholding/Withdrawing life-supporting treatment</td>
<td>15</td>
<td>8</td>
<td>23 (37.10%)</td>
</tr>
<tr>
<td>Cardiopulmonary resuscitation/Do-not-resuscitate</td>
<td>12</td>
<td>9</td>
<td>21 (33.87%)</td>
</tr>
<tr>
<td>Unclear goal of medical care</td>
<td>5</td>
<td>13</td>
<td>18 (29.03%)</td>
</tr>
<tr>
<td>Disagreement between health care team members</td>
<td>7</td>
<td>9</td>
<td>16 (25.81%)</td>
</tr>
<tr>
<td>Individual autonomy/Family autonomy</td>
<td>1</td>
<td>1</td>
<td>2 (3.23%)</td>
</tr>
<tr>
<td>Treatment refusal</td>
<td>2</td>
<td>0</td>
<td>2 (3.23%)</td>
</tr>
<tr>
<td>Legal issues</td>
<td>2</td>
<td>0</td>
<td>2 (3.23%)</td>
</tr>
<tr>
<td>Complementary and alternative medicine</td>
<td>1</td>
<td>0</td>
<td>1 (1.61%)</td>
</tr>
<tr>
<td>Hospice/Palliative Care</td>
<td>0</td>
<td>1</td>
<td>1 (1.61%)</td>
</tr>
<tr>
<td>Negligence</td>
<td>1</td>
<td>0</td>
<td>1 (1.61%)</td>
</tr>
<tr>
<td>Euthanasia</td>
<td>1</td>
<td>0</td>
<td>1 (1.61%)</td>
</tr>
<tr>
<td>Surrogacy</td>
<td>0</td>
<td>1</td>
<td>1 (1.61%)</td>
</tr>
</tbody>
</table>

Abbreviation List: HCEC=health care ethics consultation.
Example Table 2

<table>
<thead>
<tr>
<th>Issues</th>
<th>HCEC</th>
<th>UC</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagreement between health care team and family members</td>
<td>22</td>
<td>15</td>
<td>37 (59.68%)</td>
</tr>
<tr>
<td>Withholding/Withdrawing life-supporting treatment</td>
<td>15</td>
<td>8</td>
<td>23 (37.10%)</td>
</tr>
<tr>
<td>Cardiopulmonary resuscitation/Do-not-resuscitate</td>
<td>12</td>
<td>9</td>
<td>21 (33.87%)</td>
</tr>
<tr>
<td>Unclear goal of medical care</td>
<td>5</td>
<td>13</td>
<td>18 (29.03%)</td>
</tr>
<tr>
<td>Disagreement between health care team members</td>
<td>7</td>
<td>9</td>
<td>16 (25.81%)</td>
</tr>
<tr>
<td>Others</td>
<td>8</td>
<td>3</td>
<td>11 (17.74%)</td>
</tr>
</tbody>
</table>

Abbreviation List: HCEC=health care ethics consultation.

Chi-squared test with a $p$ value of 0.113.

<Minor Essential Revisions>

1. We added “Although the total of Elixhauser comorbidity measures is not an acute severity score, it is the only severity of illness which can be collected in all the three intensive care units” in the first paragraph of the “Data Collection” sub-section (highlighted by yellow).
2. We followed your suggestions that non-parametric statistical methods, such as Mann-Whitney test and the Chi-squared test, should be used for this small sample size, skewed data. We did the statistical analysis again using non-parametric methods. Please check all the highlighted numbers in Table 2 and in the “Results and discussion” section.

3. We actually intended to mix the total of the physicians’ HCEC requests and the total of the nurses’ HCEC requests. However, we decided to follow your suggestions to show the number (percentage) of the three leading ethical issues by physicians and by nurses.

<Discretionary Revisions>

1. We tried our best to follow your suggestion to cut some discussions. However, the other reviewers also gave us a great deal of helpful feedback, which we must follow in the revised manuscript. Therefore, due to adopting so many good suggestions made by all reviewers, the revised manuscript may be slightly longer. We hope that you accept the length of the manuscript for having made these positive additions to the manuscript.

2. We have followed your suggestions to correct the spelling/grammatical errors.

<Responses to Questions Proposed in the Manuscript File>

1. Your statement regarding “Not sure of the style requirements for this journal but this should in general be Discussion”: as requirement of this journal, the authors are asked to make results and discussion in its own section (called “Results and Discussion”).
Therefore, we make a brief summary about the main findings following the results (usually the “Main Findings” is located at the beginning of the “Discussion”).

2. Your concern regarding “You do not know this - you only know that the mortality at discharge was similar, you do not report post discharge wellbeing or mortality”: actually that sentence in our manuscript is a summary of the three studies made by Schneiderman, not a brief report of our study.

We would like to thank you again for your effort and time in review of our study. In summary, we are grateful for how your feedback has benefited and advanced our approach to the study. We hope that the current version of this edited manuscript is suitable for publication in this journal.

To Referee 2, Dr. Asai
Dear Dr. Asai,

Thank you for your thoughtful comments on our work. Our point-to-point responses to your comments are as follows:

<Major Compulsory Revisions>

1. In the last paragraph of the “Background” section, we added “HCEC is still in its infancy in East Asian countries, as well as in Taiwan. In 2008, Fukuyama et al. reported the first small team HCEC services started in October 2006 in Japan, which was also the first formal HCEC published in an academic international journal from East Asia. Until now, there is no formal report published in academic international journals in regarding HCEC services in the health care institutions in Taiwan.”

2—1 Thank you for reminding us of the qualification issues. Based on your suggestions, at the beginning of the second paragraph of the “Study Design” sub-section, we added “HCEC can be conducted by a hospital ethics committee, a small group of ethics consultants, or an individual ethics consultant. In our study, we conducted HCEC by individual ethics consultants. The qualifications, skills and knowledge of an individual ethics consultant have been proposed by Aulisio et al. Our individual ethics consultants all have doctoral degrees, received more than a decade of training in clinical medicine, and completed more than 20 hours of clinical ethics educational courses per year.” In addition, following the noted paragraph, we pointed out that
HCEC in this study was conducted mostly by adopting the steps proposed by Aulisio et al.

2—2 In the last paragraph of the “Results and Discussion” section, we added “Before this study was conducted, HCEC services were not formally announced to National Taiwan University Hospital. There were only few formal and informal HCEC conducted by individual ethics consultants who had several years of clinical ethics training as well as medical training. Currently, given that HCEC services have been formally announced to National Taiwan University Hospital and the institutional supports were in place for HCEC services, a group of individual ethics consultants (composed of physicians, nurses and social workers) are conducting daily HCEC services, and, as a result, healthcare professionals’ requests for HCEC are dramatically increasing.”

2—3 Thank you for your comments. Actually we conducted this study by following the study design of two influencing studies executed by Schneiderman et al.: the first one published in Critical Care Medicine in 2000; the second one published in Journal of American Medical Association in 2003. Both of the two studies used the study design of randomized controlled trial (RCT) with the intent-to-treat principle. Their studies provided us a good ethical justification to support our study design using randomization. Furthermore, the second ethical justification for our study design is the principle of Clinical Equipose, implying that there should exist no decisive evidence that the intervention being tested will be superior to existing treatments or
effective at all. Therefore, even if there is convincing evidence showing that HCEC is beneficial to patients with ethical conflicts in the U.S., there is no decisive evidence that HCEC is superior to usual care in Taiwan. This provides the second ethical justification for our study design using randomization.

2—4 We amended the “Study Design” sub-section, by adding “based on a random number table,” and “If a case was assigned to the HCEC group but the attending physician did not want to receive HCEC, the preference of not receiving HCEC was honored. If a case was assigned to the UC group but the attending physician wanted to receive HCEC, the preference of receiving HCEC was honored.” We did not deprive any case of receiving or not receiving HCEC.

2—5 Thank you for pointing out this issue. While starting HCEC, we did not have very sophisticated reasons to support applying ethics facilitation approach to conducting HCEC. The only simple reason is that, so far as we have gathered, this is the most popular approach to conducting HCEC in the U.S., which has the most well-developed HCEC approaches in the world. Although we had concerns regarding applying ethics facilitation approach to medical encounters in Taiwan (we discussed this in the 3 of this point-to-point response following your suggestion), we believed that we should first follow the approach which is already recognized in the literature, and then modify it after having numerous experiences conducting HCEC.

2—6 We assumed that the options proposed by the individual ethics consultant in HCEC
were morally acceptable, which means that the option does not offend common
people’s beliefs. Noting your feedbacks, we also identified some confusions regarding
the consensus achieved. Therefore, at the end of “Data Collection” sub-section, we
added “A consensus regarding the goal of medical care was achieved in the HCEC
group if any of the morally acceptable options suggested by the individual ethics
consultant was followed, and in the UC group if patients/family members and health
care team members agreed on any options for the goal of medical care. Health care
team members were contacted about whether there was a consensus on the goal of
medical care after the onset of medical uncertainty or conflict regarding value-laden
issues in the UC group, or after the HCEC was done in the HCEC group.”

3. It is very difficult to clearly define the “Western countries” as well as to clearly point out
the current clinical ethics norms in Taiwan and those in the Western countries. For
pointing out the cultural difference between East Asian countries and North
America/Europe focusing on the locus of authority in medical decision-making, we added
a sub-section of “Cultural Differences in Conducting Health Care Ethics Consultation”
containing the following paragraphs: “Our ethics consultants were encouraged to conduct
HCEC following the ethics facilitation approach as proposed by Aulisio et al. Part of the
rationale to support this approach to conducting HCEC in the U.S., according to Aulisio
et al., are that the U.S. is a pluralistic society, and the main societal value is individual
autonomy. To honor each moral stakeholder from different racial/ethnic backgrounds, and
also to uphold the societal value of respecting individual autonomy, the voice of each
moral stakeholder surrounding the ethical conflict should be heard, and his/her
preferences should be respected. Therefore, ethics facilitation approach for conducting HCEC is highly suggested in the U.S.”

And also added “However, the ethics facilitation approach to conducting HCEC in medical encounters in Taiwan might be of concern because individual autonomy may not be the main societal value. For several thousand years, Confucian philosophy has deeply influenced societal values, and ethical considerations in East Asian countries such as Taiwan [24]. One phenomenon rooted in Confucian philosophy highlighting the difference between East Asian countries and North America/Europe is the locus of authority in decision-making: North America/Europe demands and promotes the value of individual autonomy; East Asian countries typically honor and uphold the value of family autonomy [25]. Although the ongoing westernization of East Asian biomedical ethics in Taiwan is convincing, family autonomy seems to remain as the main societal value [21]. As such, the appropriateness of applying the ethics facilitation approach to conducting HCEC in Taiwan’s medical encounters should be further deliberated.”

We would like to thank you again for your effort and time in review of our study. In summary, we are grateful for how your feedback has benefited and advanced our approach to the study. We hope that the current version of the edited manuscript is suitable for publication in this journal.

To Referee 3, Dr. Fanari
Dear Dr. Fanari,

Thank you for your thoughtful comments on our work. Our point-to-point responses to your comments are as follows:

1. Our response to your feedback stating “First, although it is important to report the role of ethics committees in achieving consensus among medical personnel; that does not show the impact of involving this committee on the patient and patients' families in resolving any discrepancy in understanding medical and moral choices and decisions”: this study was to evaluate the outcomes of HCEC (the last paragraph of the “Background” section) conducted by several individual ethics consultants, not by a hospital ethics committee. Among the 35 cases which received HCEC (31 from the HCEC group and 4 from the UC group), the ethical conflicts of two cases could not be resolved by the individual ethics consultants, and with further requested HCEC to be conducted by a group of ethics consultants, not the entire hospital ethics committee. Our study did not examine the outcomes of HCEC conducted by the hospital ethics committee as indicated by achieving a consensus regarding the goal of medical care. Therefore, we do not have data regarding the impact of between the consultation conducted by the hospital ethics committee and the patient and patients' families in resolving any discrepancy in understanding medical and moral choices and decisions. We have data regarding the influence of HCEC conducted by the individual ethics consultants on achieving the goals of medical care, which is shown on Table 2 of this manuscript. We sincerely hope that you appreciate the limitation of this study. We recognized that the influence of HCEC conducted by the
hospital ethics committee on achieving the goals of medical care was also crucial, and may be adopted as an important direction of future research in HCEC.

2. Our response to your feedback stating “Second, a more detailed clarification on the measures taken by the usual care group is needed especially reporting any differences in the measures used in areas of clarification of goals of care and achieving agreement between family parties between (HCEC group) and (UC group can be helpful)”: thank you for calling our attention to this necessary clarification. Accordingly, in the “Data Collection” sub-section (highlighted by yellow) we added the following: “A consensus regarding the goal of medical care was achieved in the HCEC group if any of the morally acceptable options suggested by the individual ethics consultant was followed, and in the UC group if patients/family members and health care team members agreed on any options for the goal of medical care. Health care team members were contacted about whether there was a consensus on the goal of medical care after the onset of medical uncertainty or conflict regarding value-laden issues in the UC group, or after the HCEC was done in the HCEC group.” (highlighted by yellow) in the “Data Collection” sub-section. We hope this clarifies how achieving the goals of medical care was defined in the HCEC group and the UC group.

3. Before conducting this study, our research team decided not to adopt its costs as outcome measurements in this study. We did this because Mills et al. published a paper in Cambridge Quarterly of Healthcare Ethics, arguing that evaluating ethics consultation on the basis of cost is not a good idea (Mills et al. 2005). Therefore, we did not incorporate
cost as an outcome measurement in this study. Nevertheless, the four outcome measurements used in this study (the total ICU stay, the total hospital stay, the post-conflict ICU stay, and the post-conflict hospital stay) can partly reflect medical resources allocation.

We would like to thank you again for your effort and time in review of our study. In summary, we are grateful for how your feedback has benefited and advanced our approach to the study. We hope that the current version of the edited manuscript is suitable for publication in this journal.