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Title	Supporting shared decision-making about cardiopulmonary resuscitation using a video-based decision support intervention in a hospital setting: findings from a multi-site, before-after pilot study
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Reviewer 1	Emily Ross
Institution	Department of Biomedical Physiology and Kinesiology, Simon Fraser University, Burnaby, BC
General comments (author response in bold)	<p>I found the manuscript/study results interesting to read and think that the results would be of interest to other hospitals—especially as the video is freely available to use.</p> <p><b>We thank the reviewer for the positive comments about our work. (p. n/a)</b></p> <p>Introduction</p> <p>I think that the background could use a little more information to set up the study. For example, is the issue that there are too many patients choosing CPR based on inaccurate knowledge? That it should not be considered the default? That patients don't realize they have a choice and what the choice entails? The hospitals don't have enough time or the right systems to help patients make this decision? It would help to clarify what the "interventions they would receive if CPR is performed" (page 4 line 15).</p> <p><b>We thank the reviewer for the helpful suggestions. The main point we were trying to make is that patients need more accurate information upon which to base decisions about CPR. We have removed the content about the "default" status of CPR in hospitals and focused the opening paragraph of the Introduction on insufficient or inaccurate patient knowledge about CPR. We have also included the types of interventions patients would receive if CPR is performed. (p. 5)</b></p> <p>Why did you choose to do a video decision aid instead of another format of decision aid? What other decision aids have been tried in Canada (if any) and why have they [not] been successful?</p> <p><b>We chose to develop a video decision aid because low health literacy may be an important factor leading to poor understanding of the CPR decision. Others have found that video-based images can be a useful way to support decision making. For instance, patients and their substitute decision makers were more likely to agree about the patient's preferences for CPR after viewing a video decision aid compared to a verbal description alone. (Volandes AE, Mitchell SL, Gillick MR, Chang Y, Paasche-Orlow MK: Using Video Images to Improve the Accuracy of Surrogate Decision-Making: A Randomized Controlled Trial. Journal of the American Medical Directors Association 2009, 10: 575-580.)</b></p> <p><b>We have added our justification for a video-based format to the Introduction along with the above citation.</b></p> <p><b>We are not aware of other decision aids that have been tried in Canada to support decision making about CPR. (p. 6, reference #12)</b></p> <p>Page 4, Line 52: In the systematic review, regarding change in participants' preferences for CPR, is the goal to change participants' preferences?</p> <p><b>The primary goal is to improve knowledge and clarify values so that patients'</b></p>

preferences are correctly informed and aligned with their values. Given that the majority of patients do not have accurate knowledge of CPR and are often unclear about their own values then, yes, ultimately the expectation would be that patients' preferences would change. (p. n/a)

Page 5, Line 10: In your objective statement, can you clarify what you mean by "effectiveness". What factors are included in this decision aid being effective?

**We have added to this sentence in parentheses the specific outcomes we used to assess effectiveness (reduced decisional conflict, increased knowledge, and change in medical orders for CPR). (p. 6)**

Methods

In general, I think the study design is appropriate. I listed some areas that I found could use some more detail and/or were a little confusing.

**Thank you – see below (p. n/a)**

Page 5, 26: Name the research ethics boards involved (i.e. were they only hospital ethics boards or university ethics boards as well).

**Hamilton Integrated Research Ethics Board and McGill University Health Centre Research Ethics Board (both are combined hospital and university ethics boards). (p. 7)**

Page 5; Line 33: Can you example why you selected these age ranges? Also, in the appendix, you list that one of the chronic illness was end-stage dementia. How many of these patients are able to give informed consent?

**The age ranges we used are consistent with previous research by our group in the area of communication and decision-making during serious illness and identify a group of patients with a high risk of death for whom decision making about CPR in hospital would be very relevant. See also our response to Editor Comment #9 and additional references #15, 16.**

**Patients with end-stage dementia would meet inclusion criteria but then would have been excluded because of cognitive impairment; however, family members of such patients could then be screened for eligibility and approached for enrollment so it was still important to include end-stage dementia as a patient eligibility criterion (see also our response to Editor Comment #12). (p. 7, references #15, 16)**

Page 5, Line 45: Can you clarify which family members were approached? Family members of patients who did not provide consent, or just patients who did not meet eligibility criteria and that the study staff did not get to approach for whatever reason? Can you include more rationale for why you included family members and if these family members were representative of the ones that would be making this decision in real life?

**See our response to Editor Comment #12 about which family members were approached.**

**We believe it was important to include family members because, similar to our approach to enrollment for this study, when patients are not able to communicate then clinicians will need to engage family members in decision-making about CPR instead. (p. 7)**

Page 6: Line 26: Is there a reason why the prototype was piloted with community dwelling adults instead of your target population?

**Initially, the decision-aid was not designed for use with a specific patient population but instead for potential broad applicability. Since our study focused specifically on a hospitalized population, we included in an assessment of the tool by our study participants and found that it received good ratings of acceptability, clarity, and usefulness. (Table 2)**

Page 6, Line 52: What was the rationale for approaching patients who had been on the ward for 2 to 7 days? In figure 1, there were 4 patients who were > 120 hours from hospital admission. This is only 5 days not 7. Were patients recruited between 2 to 5 days instead (or perhaps I'm just misunderstanding something)?

**Thank you for pointing out this arithmetic error. The correct range was 2 to 7 days and this has been corrected in Figure 1. (Figure 1)**

Minor comment, you said that the video was designed to be shown on a computer screen (page 6, line 2), but you showed it on a tablet (or laptop) (page 7, line 47). You might want to clarify what you mean by computer screen (i.e. did you mean a digital device? Are videos designed differently for a laptop versus a tablet?)

**Yes. We meant that it could be viewed on a digital device and have changed this in our revised manuscript. The video is not formatted differently for laptop or tablet and is easily viewable on either device. (p. 8)**

Page 8, line 15: Were the post-video questionnaires administered in person? Or were they done over the phone or mail if the participant had been discharged (perhaps no one had been discharged yet)?

**The questionnaires were administered in person if patients had not yet been discharged and over the phone if patients had been discharged. (p. 11)**

Did you decide to look at whether the patients who had a discussion with a clinician had different change scores than those that did not (your sample may not be big enough)

**We did not pre-specify any subgroup analyses (see response to Editor Comment #21). We believe there would have been an appreciable risk of spurious conclusions due to multiple comparisons and also we agree with the reviewer that the sample size of evaluable participants per subgroup would be small. (p. n/a)**

## Results

The results seemed reasonable. The tables were generally good although I would make sure that there is not too much repetition between the text and the tables.

**We have revised the main text of the Results section to minimize repetition between text and figures/tables. (p. 13)**

Table 1: How does your study population compare to the general population on these wards?

**We did not collect demographic data for the general population on the wards but presume that, because of our eligibility criteria, that they were on average older and sicker than the general population on the wards. (p. n/a)**

Table 2: I just wanted to confirm that some of the questions were on a 1-5 scale, while others were 1-4, and the overall scale is 1-5? I'm assuming that the overall score takes into account that for some of the questions, a 3 is the best score?

	<p>It is correct that different scales were used for different questions. The overall score is a separate standalone item that participants were asked to answer on a 1 to 5 scale and is not derived from the responses to previous questions. To help clarify this, in the revised Table 2, we have included the full wording of that question. Also, in response to Editor Comment #13, we have included study questionnaires in an Online Supplementary File, so this should now be clearer. (Table 2, Supplementary File)</p> <p>Did you look at whether there were any differences in the family members versus patients' responses?  <b>See our response to Editor Comment #21 about subgroup analyses. (p. n/a)</b></p> <p>Interpretation</p> <p>What are your reasons for why the Canadian context would be different from the US context? And then why your results are generalizable to the Canadian context and not just your two hospitals? (you did briefly touch on this your limitations)  <b>We have simplified our description of the other studies done in other settings or jurisdictions and have simply stated that our study findings are consistent with the other studies. We have acknowledged the limitations to generalizability of our findings in the "limitations" section of the Interpretation section. (p. 20-22)</b></p> <p>You say that your findings suggest that the video can be embedded into the work flow? What supports this as you had a separate research assistant show the video?  <b>This is a good point. We have revised the corresponding sentence in the Interpretation section to now read:</b>  <b>"Our findings suggest that, with the assistance of research personnel, our CPR Video Decision Aid can be embedded into clinical work flow on busy medical wards ..." (p. 21)</b></p>
<b>Reviewer 2</b>	Myriam Gagné
Institution	Knowledge Translation, Education and Prevention Chair in Respiratory and Cardiovascular Health, Laval University, Québec, Que.
General comments (author response in bold)	<p>There are minimal standards for certifying decision aids (Joseph-Williams 2013). From my understanding, the cardiopulmonary resuscitation video may not fulfill the sixth qualifying criteria: "the interventions should help patients to clarify values" (Joseph-Williams, 2013). Consequently, I wonder whether the cardiopulmonary resuscitation video, which is herein described as a decision aid, should be considered as a decision box instead (Giguere 2014, 2012).</p> <p><b>It is true that the video itself does not include a value clarification component. However, our study intervention included, after watching the video, a participant worksheet that <i>does include</i> a value clarification exercise; therefore, our study intervention does meet criteria for a decision-support intervention as a whole and we have adjusted language throughout our revised manuscript to reflect this. Specifically, in the revised manuscript, we now refer to the video itself as the "CPR Decision Video" and have described the overall study intervention (CPR Decision Video, paper-based values clarification exercise, follow-up conversation with clinician) as a decision-support intervention. (See also response to Reviewer 2, Comment #4 below) (Throughout manuscript)</b></p>

The introduction section is well written and stresses the importance of developing a decision aid about cardiopulmonary resuscitation. At the end of the section, however, I would suggest the author reword their last sentence, since a before-and-after study cannot be used to assess the effectiveness of any intervention. I would also suggest amending the remaining of the text accordingly.

**We have modified the manuscript accordingly to re-frame it as a pilot study (see response to Editor Comment #1). (p. 6 and throughout manuscript)**

Could the authors provide us with the ethics committee approval number and ClinicalTrials registry number?

**Hamilton Integrated Research Ethics Board approval # 14-545**

**McGill University Health Centre Research Ethics Board approval # 14-331-PSY**

**This study was not registered with ClinicalTrials.gov or another registry of randomized controlled trials. (p. 7)**

As I said above, there are minimal standards for certifying decision aids (Joseph-Williams 2013) and I am not sure whether or not the cardiopulmonary resuscitation video fulfill the sixth qualifying criteria, that is: “the interventions should help patients to clarify values” (Joseph-Williams, 2013). Altogether, the intervention components – video, values clarification worksheet, and follow-up discussion – could be described as a decision support intervention, however.

**We have re-framed the nature of our intervention throughout the manuscript to reflect this. Also see response above to Reviewer 2, Comment #1 (Throughout manuscript)**

Although the cardiopulmonary resuscitation video is freely available online, I would suggest the authors to explicitly report the index decision that is targeted by their decision support intervention. Within the article, I also suggest stating the options that are discussed when describing their decision support intervention, even though these options are listed in Appendix 2.

**We have added this information about options (CPR if the heart stops, continue current care plan but no CPR, or unsure) when describing the baseline assessment of decisional conflict and their associated preference regarding CPR. (p. 9)**

Follow-up discussions between physicians and patients (or their family members) were encouraged as part of the interventions. Were physicians trained in sharing health decisions with their patients? If so, should such training be described as part of the intervention components?

**Clinicians were not specifically trained on CPR discussions for this study. We have added an explicit statement to this effect. (p. 10)**

I would like to know how the acceptability scores were derived from the questionnaire items listed in Table 2? For some items, e.g, balance of information about cardiopulmonary resuscitation, the best available score is 3/5, whereas for other items, e.g. helpful in making decisions about cardiopulmonary resuscitation, the best available score is 4/4. For other items, e.g. recommend to other, the scores can range from 1 to 4? How were these different scales taken into account when calculating the overall acceptability rating on a 5-point Likert scale?

**The overall acceptability item was a separate global rating question and not**

a derived score based on previous responses. We have clarified this in our revised manuscript by including the actual text of the question in Table 2. The full questionnaire is also now included in Appendix 5. (see also our response to Reviewer #1, Comment #16) (Table 2, Supplementary File)

Also, are the distributions of the acceptability subscores gaussian? Should the acceptability data be summarized using frequencies and percentages, instead of means and standard deviations? I think that frequencies and percentages would help supporting your conclusions.

**We thank the reviewer for this helpful suggestion. Indeed, the distribution of several items on the acceptability questionnaire are skewed to the right and not Gaussian. We have revised Table 2 to report frequencies and percentages instead. (Table 2)**

Is the knowledge questionnaire assessing memorization or comprehension of knowledge about cardiopulmonary resuscitation? Additionally, the knowledge questionnaire should have been completed 48 hours after viewing the video. Was there any protocol deviation, e.g. could the questionnaire have been filled immediately after viewing the video?

**We did not systematically capture data on protocol deviations but are not aware of any instances where study nurses administered follow-up questionnaires immediately after the video.**

**Given that the knowledge questionnaire was administered 48 hours or more after viewing the video, we believe that we are testing more than immediate recall or memorization. However, it is true that the questions on the knowledge questionnaire did not ask participants to apply what they learned to other situations. So, we would agree with the reviewer that the questionnaire focused on comprehension of key facts related to CPR. (p. n/a)**

Could the authors report the method used to calculate the Cohen's effect size, for instance, by providing a reference?

**Cohen's effect size is calculated as the difference between two means divided by the pooled standard deviation for the data. We have added this description and the following reference in the Statistical Analysis section of the Methods:**

**34. Cohen J. A power primer. Psychol Bull 1992;112:155-9.**

**(Note: we discovered some minor computational errors in our original reporting of Cohen's effect size for change in knowledge score and decisional conflict and have updated these in the Results section; none of the P values have changed.) (p. 11, reference 34, p. 18, Table 3)**

The authors report using complete case analysis, that is: per protocol analyses, to assess the changes in knowledge and decisional conflict scores. Which statistical models were used to estimate these changes?

**The reviewer is correct that our primary analysis was a complete case analysis. We used paired t-tests to assess within participant changes in knowledge and decisional conflict before and after the study intervention. (p. 11)**

Also, could the authors also provide intention-to-treat analyses by using, for instance, mixed effects models? Mixed effects models, conducted per protocol and

by intention-to-treat, could help assess whether or not there might be a selection bias resulting from losses to follow-up.

**See response to Editor Comment # 4 above. (p. 12, Appendix 4)**

From the data presented in Table 3, it appears that mean decisional conflict score and subscores might not be following gaussian distributions. The distribution of decisional conflict scores rather seems skewed (as other authors reported). A log transformation could be useful and, if this strategy is successful to normalize the data, the authors should provide geometric means and geometric mean ratios.

**We thank the reviewer for this interesting suggestion. The relevant data to examine and that are the basis of the paired t-test are not the scores themselves but the within person differences in scores before versus after the study intervention (i.e., null hypothesis is a mean of within person differences = 0). We have created histograms to enable assessment of the distribution of the data: specifically, the distribution of the differences in total decisional conflict score and the distribution of the differences in the subscores (see Figures at the bottom of this document, below this Table). On visual assessment, although there may be some slight deviations from normality, we do not believe they are large enough to justify the added complexity for readers of using log transformation and using geometric means or mean ratios. (p. n/a)**

The percentage of individuals with a medical order for cardiopulmonary resuscitation seems to remain high at the end of the study. Could the authors discuss about that point?

**In the study by Kapell Brown (ref #26) that evaluated the same CPR video decision aid as our study, but in an outpatient nephrology setting, the percentage of participants with a medical order for CPR before and after watching the CPR Video Decision Aid was 86% and 72%, respectively. This is similar to the percentages of 71% and 63% that we observed before and after our study intervention. These post-intervention percentages are higher than reported in the intervention arm of the randomized controlled trial conducted in a U.S. teaching hospital by El Jawahri (81% and 43% after). Presumably this is due to between-study differences in the study population, intervention, or outcome assessment methods, but we do not believe it would add much value to the manuscript to attempt to speculate about the multiple reasons why these differences may have occurred or what post-intervention percentage of CPR orders would be too high, appropriate, or too low. (p. n/a)**

A high proportion of eligible patients and family members were not approached; the authors acknowledge this limitation. Do the authors suspect a selection bias arising from the selection of participants in the study? What would be the effect of such resulting bias?

**It is possible that there is a selection bias arising from the selection of participants in the study. It is difficult to hypothesize what would be the effect of such a bias; however, to the extent that non-participating but otherwise eligible individuals had different views about the value of life-prolongation or CPR, this may have affected our study findings. We agree that this is a limitation of our study and have noted that the potential selectivity of our study sample may limit the generalizability of our findings. (p. 22)**

Did you collect and analyze qualitative data that would support or expand your quantitative findings? If not, I would discuss this point.

**We did not collect any qualitative data to expand on our quantitative findings and agree with the reviewer that this may provide useful additional information. We have noted this in the concluding “future directions” paragraph of the Interpretation section. (p. 23)**

Is it possible that a cointervention have biased the observed results? How is usual care defined in these hospital settings?

**Observational studies of communication and decision-making about goals of care and life-sustaining treatments in similar patient populations in a hospital setting have found very low levels of engagement by clinical teams in this process of care (refs # 15,16). Furthermore, there were no additional initiatives being undertaken during the study period at either site that were intended to promote shared decision-making about CPR. Therefore, we believe that substantial co-intervention was unlikely and have added this point and cited these references in our revised manuscript; at the same time, we have still acknowledged this as an important limitation of our before-after study design. (p. 22)**

I suggest additional analyses. If necessary, please review your conclusions.

**We thank the reviewer for the thoughtful suggestions about additional analyses. After conducting the additional analyses (see above), our conclusions have not changed in a material way, but we have discussed the potential risk of bias due to missing outcome data in our revised Interpretation section. (p. 22)**

Although I believe that there is still room for improvement, I acknowledge that this article by You et al. is original and useful in advancing the field of shared decision-making. I look forward to reading another version of this manuscript.

**We thank the reviewer for the positive comments about our work and thoughtful review of our manuscript (p. n/a)**