Article details: 2020-0022	
Title	Evaluation of a program using a physician assistant and an electronic patient-provider communication tool to facilitate discussions about goals of care in elderly hospitalized patients: a pilot study
Authors	Monica Monchis BScHons BScPA CCPA, Chris Martin MD, Giulio DiDiodato MD MPH PhD
Reviewer 1	John You
Institution	Trillium Health Partners, Division of General and Hospitalist Medicine
Reviewer comments and author response	**Reviewer comments** Thank you for the opportunity to review this paper that reports the findings from a single centre pilot study to assess the feasibility of an intervention (e-tool and physician assistant led structured goals of care discussion) to improve decision making about life sustaining treatments amongst elderly (age 79 years or older) patients in hospital. The study addresses an important issue in the care of older patients in hospital. I have some comments that I hope the authors will find helpful in strengthening the paper: Major comments 1. Given that this is a pilot study and that the stated aim is to assess feasibility of the intervention, suggest explicitly stating in the abstract and at the end of the Introduction what is or are the primary feasibility outcomes. In the Methods section, 5 outcomes are listed. The first 3 are related to feasibility (percentage of eligible patients who did not consent, percentage of eligible patients who received the intervention, time to conduct a goals of care discussion). 2. Because the target population for this study excludes patients who had already chosen supportive or comfort care, the authors seem to be: (i) assuming that decisions for supportive/comfort care were based on a high quality decision making process (I am not sure that this is typically true based on my own clinical experience as a hospitalist) and so would not benefit from the study intervention, or (ii) implying that it is more important to prevent errors of over-treatment (e.g. with CPR, ICU admission) than it is to prevent errors of under-treatment. I think there is a risk that the motivations of the authors could be “twisted” by readers or the media (e.g., this intervention has been designed to “get a DNR in patients deemed to be inappropriate candidates for ICU treatment”) and that it is very important for the authors to justify why this study excluded patients who already had an order for supportive/comfort care. 3. It seems to me that a critical aspect in assessing the feasibility of this intervention would be its acceptability to patients and SDMs. There is one sentence in the Results section presenting anecdotal evidence that patients/SDMs “were uniformly satisfied with the content of the PCGCD e-tool and found the information easy to understand and helpful in guiding their treatment decisions.” Because there are no quantitative or qualitative data that would allow a reader to judge the credibility of this statement, it is hard to truly know how acceptable the intervention is to patients/SDMs. Furthermore, it is quite possible that the approximately 90% of eligible but non-participating patients could have had different views about the tool or goals of care discussions in general and might have been “avoided” (consciously or sub-consciously) by the physician assistant when selecting patients for the intervention. Suggest acknowledging these

	important limitations of the study in the Discussion section. 4. The 8 questions about values (rated on a scale of 1 to 10) that were incorporated into the e-tool were not the subject of our CMAJ 2014 paper (ref #19). Details about these 8 values questions and patient/SDM responses to these questions were reported in our paper in BMJ Supportive Palliative Care (ref #31), so this should be corrected in the table in the appendix describing the e-tool contents. 5. Also, related to these values questions, in the table describing the e-tool contents, the authors state that many of the 8 values questions resulted in decisional conflict and that we reported a similar experience in ref #31. However, we did not report on decisional conflict in ref #31 (decisional conflict is a measure of an individual's uncertainty in making a given choice). I wonder if the authors don't really mean "decisional conflict" here but instead are referring to the fact that patients and SDMs in that study (ref #31) did not agree on the answers to these 8 values questions? Agreement and decisional conflict are different constructs. 6. Even more importantly, the authors stated in the description of the e-tool (in appendix) that they only consistently asked 2 of the 8 values questions because many of the questions resulted in decisional conflict. I am puzzled why questions that might generate rich discussion between patient and SDM to help clarify values would be left out of a goals of care discussion. Similarly, if a given question provokes uncertainty (or a strong emotional response) in a patient or SDM, why is that something to avoid? Again, would it not create an important opportunity to further explore and clarify the patient or SDM's values and ultimately lead to a better decision about treatment? 7. Also related to these values questions, Table 1 reports that enrolled patients did not answer item #4 almost half of the time (45.9%). And the number of missing responses for item #7 is not reported in Table 1 (that row is blank), but based on the other percentages listed in the Table, also seems to be about 50% patients did not answer that question either. In our paper, ref #31, we had higher response rates than this (72% to 95%). Why was the response rate for these 2 questions only approximately 50%? The authors are claiming that their intervention is "person centered". However, if values are not being elicited half of the time and most of the values questions (i.e. 6 of the 8 values statements) are being omitted altogether, I am not sure if it is accurate to describe the intervention as being "person centered". Based on best practices in shared decision-making, values should inform treatment decisions. 8. Related to the above point, it is also unclear how the PA incorporated the patient's values into decision making about life sustaining treatments? For example, if a patient rated that avoiding machines was not at all important to them and that prolonging life was extremely important to them, a goal consistent/value-concordant decision for that person would be for "full CPR" – would the PA make that treatment recommendation for a patient in this scenario? Minor comments 1. There are a lot of non-standard abbreviations throughout the manuscript that make it difficult to read. Suggest minimizing these as much as possible and just spelling out in full. 2. The first paragraph of the Discussion was a pretty good summary of the rationale for this work and seemed like it might belong better in the Introduction. 3. Since the intervention is focused on goals of care discussions and not advance

	care planning, suggest simply removing the content about advance care planning from the Introduction. 4. The second paragraph of the Discussion was largely about the rationale for the inclusion criterion of age 79 years or older and might more appropriately belong in the corresponding text of the Methods section where the inclusion criterion is being presented for the first time. 5. The Discussion section seemed somewhat short and under-developed. It typically would begin with a summary of key findings from this study (i.e., what were the main feasibility outcomes and based on those findings did the investigators deem that their intervention was feasible or that it might require some more modification or further research, e.g. about its acceptability, before moving to a larger evaluative study/RCT?). It is also missing a paragraph discussing the main strengths and limitations of the study (see above comments re: important limitations). 6. It would be interesting and relevant to know how the clinicians (e.g. the attending physicians for the 37 patients enrolled in the study) felt about the intervention. Presumably no data were collected from clinicians? This information would be of interest before proceeding with a larger evaluative trial (see comment #8 below as well). 7. Results section, first para (page 10): I think the correct denominator for eligible patients = 445, not 408, since the 37 patients who were enrolled still need to be counted in the denominator. If so, then the correct recruitment rate is 37/445 = 8.3%, not 9.1%. 8. If the investigators do plan to move ahead with a randomized controlled trial of this intervention and plan to apply for peer-reviewed funding for the RCT then I would strongly recommend that they collect some more objective data (e.g. using a survey with closed ended response options, or qualitative interviews, or a mixture of both) on the acceptability of the intervention (in a more representative sample of patients if possible), and additional pilot data demonstrating that, with some changes made to the tool or study procedures, a recruitment rate of greater than 8% can be achieved. Otherwise, with the current limitations, I think it will be very difficult to get funding to support a future RCT, since a valid criticism of a subsequent trial with a recruitment rate of approx. 10% will be that it lacks generalizability to the “real world” and so unlikely that funding agencies would be willing to spend money on such a trial. 9. In Table 1, suggest actually putting the text of “Values question 4” and “Values question 7” directly in the table, and also including directly in the table the descriptor for the anchor ratings of 1 and 10. Otherwise, it is not easily interpretable by the reader. **AUTHOR RESPONSE** 1. p5 2. Included in limitations p 18 3. Included in limitations p 18 4. Corrected in supplement 5. Removed term ‘decisional conflict’ and replaced with internally inconsistent responses where appropriate 6/7/8. Patient-centered care requires that treatment recommendations be based on experimental evidence and clinical expertise of benefit, and then these recommendations are informed by and, where appropriate, aligned with patient’s values/goals. The reviewer is conflating patient-centered care with patient-directed

	care. Patients don't dictate treatment they receive; they choose from those recommended by the evidence and clinical experts. To suggest that some missing inputs on values/goals would suggest our comprehensive approach to elicitation of resuscitation decisions invalidates it as patient-centered is misguided. According to the reviewer, providing life support to patients who value 'extending life at all costs" but who are at the end-of-life because of a life-limiting illness that is not amenable to any further treatment and so would not benefit from life-sustaining treatment as determined by evidence and intensivists' clinical expertise would be considered 'patient-centered' and 'concordant' just because the patient valued 'life at all costs'. In general, intensivists would never consider this appropriate, let alone 'patient-centered' care. Patient-centered care is informed by values/goals but not dictated by them. In addition, we selectively reported only 2 questions from the 8-items – the response rates for those 2 questions aren't representative of the response rates for all 8 questions for any single patient. Many patients, after being exposed to our comprehensive intervention, simply chose not to complete the values/goals section because they felt more than sufficiently informed and prepared to make resuscitation decisions. Their values/goals were latent but clearly observable in their resuscitation decisions Truthfully, we found this section of our intervention to be the most difficult for patients to complete as the language of the questions resulted in a lot of internally inconsistent responses. We have made many subsequent modifications to our tool and used our learnings to improve upon the values and goals section of the next iteration, both with regard to the language but also their visual representation. As regards to the patient-centeredness of our intervention, we don't believe that a different response rate on 2 questions from previously published studies in different populations in different contexts implies that our intervention is somehow not patient-centered. We engaged patients using a comprehensive, multidimensional, patient-centered approach, not just using an 8-item questionnaire, so the response rates may simply reflect that in our intervention completing this 8-item questionnaire likely had minimal attributable impact or relevance to patients' decisions about resuscitation preferences. Any resuscitation recommendations made through our program incorporated patients' values and goals but were not dictated by them. This is why an ICU clinician was chosen to lead this program for that very reason because our staff have the experience and expertise to speak to these issues and then also explain the implications of choosing these resuscitation preferences including prognoses, risks, benefits and long-term sequelae. Minor 1. majority removed 2. Revised as recommended p4/5 3. Removed as recommended p4/5 4. Revised as recommended (p7) 5. Revised as recommended (p16-17) 6. As explained in the protocol, we contacted every attending physician to get their consent to contact their patients, and the majority consented (see document). In addition, we also contacted every attending physician after the consult was done to discuss the findings and make our suggestions – all of the attending physicians accepted our recommendations. 7. see patient flow diagram (supplement) 8. Agreed – we have been modifying the process/tool to ensure reduced cognitive and time burden 9. Left as is to make table entry less cluttered

Reviewer 2	Emily Mulligan
Institution	Winchester District Memorial Hospital, Research
Reviewer comments and author response	**Reviewer comments** Thank you for allowing me the opportunity to review this paper. A couple comments: I feel like this manuscript needs a section on generalizability to other sites/ organizations. How might or might not the tool in specific or even general lessons learn be transferrable? Since the project was all about patient-centered care were there any patient reps involved in the creation/ modification of the etool? Or the study? Will there be in the larger scale? Does the patient/ caregiver get a copy of the conversation/ goals? Is there a copy that follows them if they were to be admitted somewhere else for example? What did the nurses think of this? - Nurse often feel out of the loop in research projects. Were they informed that this was happening, what did they think about it. What were the limitations of the pilot study? How will these be addressed in larger scale? Were there any balancing measures? Could benefit from a little more explanation on the 'before' so we can get a better picture of the difference. **AUTHOR RESPONSE** 1. Tool is being modified as result of pilot for subsequent study. We have commented on these limitations (p17/18) 2. Tool was beta-tested on 31 patients for their input prior to this pilot (p6) and all the input from the 37 patients/SDMs has been used to help modify the tool for the next study. We feel that direct input from 68 patient/public stakeholders far exceeds the input reported in the vast majority of studies. 3. A dictated medical note is entered into the electronic medical record so that every physician, including their primary care physician in the community, receives a copy of the discussion, and because the note is in the EMR, it can be viewed by any healthcare provider on all subsequent hospital admissions (p10 and figure 1). 4. Nurses were educated prior to implementation (p8)and nurses have the ability to directly consult our Goals of Care Program (much like they can consult a critical care outreach team) (p 17) 5. limitations section p 17/18 6. Not sure we understand what is meant by this question? 7. The 'before' is the same as would be in any hospital which is haphazard and poor conversations as described in the introduction 4/5
Reviewer 3	Jeff Myers
Institution	Sinai-Bridgepoint Palliative Care Unit, Toronto, Ont.
Reviewer comments and author response	**Reviewer comments** GENERAL - The overarching aim of the intervention is to limit EOL decision-making processes that are not adequately informed by ensuring high quality goals of care discussions (GCDs) - A key premise is that quality and content of GCD can be optimized by standardizing certain elements of the discussion

	- Validated tools and prognostic scoring systems were used to identify elements that comprised an e-tool to directly guide GCDs - In addition to using an e-tool, the three broad process components involve identifying appropriate patients, engaging with e-tool and communicating outcomes of the GCD - It's important to note that although appropriately informed treatment decisions require treatments themselves as well as their likely benefit to be understood, a critical quality gap for GCDs is the widespread lack of understanding that exists among pts with serious illness for both the incurable and progressive nature of associated diseases INTRO - A minor note re: concordance between POLSTs and care received as recent data suggests this might not be as high as previously suggested (e.g. DOI: 10.1001/jama.2019.22523) - The objective of this pilot trial is to evaluate the feasibility of using a novel e-tool designed to standardize patient-centred goals of care discussions in hospitalized patients. - Missing is a clear set of a priori outcomes that would make it not feasible for this intervention to proceed with a RCT METHODS - E-tool was developed using elements of validated tools and prognostic scoring systems - There is a minimal description of the e-tool development, specifically: o how & why specific elements were selected o how GCD elements improves the quality and content of GCDs - There is a minimal description of the training process for the PA to use the e-tool and specifically how the e-tool would be used to guide a GCD (this is critical for replication) - Core elements of the final e-tool seem to be: ▪ An item addressing health literacy ▪ Items addressing global quality of life ▪ An item addressing how much to avoid being attached to machines ▪ An item addressing strength of belief that life should be preserved ▪ Pt is informed about likelihood of surviving to d/c in general ▪ Pt is informed about a range of likelihood re: surviving to d/c if CP arrest o Notably absent is anything that addresses the underlying illness. Both incurable and progressive as concepts are disease agnostic and would strengthen the assurance that decisions are adequately informed o Excellent to include an assessment of health literacy level however no mention of how different levels altered the GCD o Script addressing the CRA prognostic tool indicates that what is messaged to patients is the only info needed to make the best possible decisions is the likelihood of discharge following a cardiac arrest - It's unclear why e-tool elements associated with decisional conflict were removed

	- There are substantive differences in the e-tool elements, Standardized Dictation Template and Script RESULTS - Given the focus on feasibility and that 3 of 5 outcomes address the process of completing a GCD, the % completion rate requires greater exploration: o In 5 mos, 37 GCDs completed (average GCD duration = 50.1 minutes) o Despite a thorough list of pre and post GCD tasks, this equates to just over 7 GCDs/month or less than 2 per week o Comments on the reported process changes are below but important to underscore concerns that a single GCD required more than 2 days to complete as this speaks directly to feasibility - Among all pts with POLST not completed prior to intervention, POLST remained not complete in ½ of exposed (i.e. 11 of 22) vs ~15% of non-exposed. This suggests there's a greater likelihood a POLST will be completed if a GCD does not happen thus requires exploration and comment - Table 3 data suggests some type of code status clarification process occurred among non-exposed. This requires exploration and comment. DISCUSSION - Would be strengthened if the three comments outlined in Results above are addressed - The pilot limitation addressed in detail is the length of time required to complete GCDs - It is clear the main feasibility issue relates to completion rate and it's likely several steps in the process will require a different approach however 50 minutes for the GCD is not prohibitively excessive and the suggested changes as outlined may risk quality of the GCD: o the two changes in methods identified are a more efficient approach to involving SDMs and a more streamlined GCD o The suggested changes to the GCD limit the elements to completion of prognostic scores and explanation of POLST options This is potentially problematic as along with the absence of illness understanding, this would make it less clear how values and pt's goals should inform decision making and further limits the patient-centredness of the intervention **AUTHOR RESPONSE** 1/5. We believe that these elements are included in the paper/supplement in adequate detail. Intro 6. We do comment on the uncertainty around the quality of the conversations that are involved in guiding resuscitation decisions documented in POLSTs (p 4/5), thus potentially contributing to their being misaligned with end-of-life care as mentioned in the reference cited. 7. objective revised (p5) 8. We did not define any a priori thresholds for any of the primary outcomes that would stop us from proceeding with a subsequent study because we did not believe that any result would do so. We fully anticipated that we would need to make modifications to the intervention before ever proceeding with a subsequent study. In addition, we also knew that this program would require substantial financial support to adopt/implement/maintain from our senior leadership team and

	without robust local evidence, this would never happen. 9. p6 and supplement 10. Revised (p5/6) and supplement 11. Revised (p8) 12. The CIHI tool is a disease-specific prognostic tool that provides patients with a visual representation of the severity of their underlying illness at a population level – it is objective and validated and was supplemented by any new insights from information provided by other clinical experts. This tool was intended to ensure that the patient's understanding of their illness prognosis was consistent with that expected from a validated tool. We used the health literacy score only to ensure that the materials in the e-tool would be understandable to the patient/SDM – it was only used as a screen in the same way the dementia/delirium was a screen for capacity to make informed decisions (supplement) Like all the elements in the e-tool, the CRA prognostic scoring system was used and supplemented by the expertise of the ICU PA regarding outcomes of CRA. The contents of the e-tool, especially, the prognostic scoring scoring were not stand-alone instruments – their information was further elaborated and explained by the clinical expert administering the intervention- this was the rationale for using a healthcare provider with icu expertise. 13. We rephrased decisional conflict to internally inconsistent – the individual elements of the e-tool had been validated as stand-alone tools, so we suspect that the impact of any one of the individual elements when combined into a comprehensive, multi-dimensional intervention was altered. In some cases, we found that some elements were of little use to patient decision making. For example, many of the patients exposed to the intervention found the language used in the 8-item values/goals questionnaire confusing and resulted in many internally inconsistent choices. Many patients simply asked to skip this section and made resuscitation preferences without overt values/goals declarations but rather were latent and observable in their resuscitation preferences. 14. The dictated script was not intended to be an exact representation of every single data element collected in the e-tool but rather the elements that were critical to summarizing the important elements of the discussion, their results and their communication in a brief but comprehensive note to attending and primary care physicians. The script was simply a guide for the PA, modified as needed to accommodate each patient. Results 15. The ICU PA also had other clinical responsibilities in the ICU – they were not dedicated to only conducting these discussions so they had to work it into their other clinical responsibilities. This is an essential observation for our program since it speaks to the resources that would be needed to support this program if left unchanged. We did speak to how we were modifying the tool without specifics to ensure that more could be completed by patients/SDM without PA involvement, so that less time would be required to complete each intervention, and how bedside nurses would be responsible for self-scheduling appointment dates and times so that the PA was not responsible for spending time doing this administrative task (p.17/18) 16. Discussed in limitations (p17/18) 17. We knew from historical data that about 50% of patients have their POLSTs completed at 48 hours after admission as a matter of hospital policy, and that many more complete them afterwards. What we are concerned with is how

	informed are these resuscitation treatment decisions documented in these forms. The percentage completed is not the important outcome from our perspective and given the number of exposed patients that chose to forego any ICU treatment compared to the non-exposed is a cause of concern that patients may not be making completely informed decisions about life-sustaining treatments and CPR. 18/19. included in discussion/limitations (p16-18) 20. We don't feel the iterations we made during the pilot affected the quality of our discussions and were based on consistent observations. In addition, the modifications were minor given the breadth of the elements included in the intervention.