Appendix 1 (as supplied by the authors): The Development and Initial Evaluation of Plan Well Guide

Decision aids are tools developed and promoted to increase high quality decisions in health care. These tools typically enhance communication about treatment options, and the benefits, harms, and outcomes associated with each option, in a manner that is easily understood by lay persons. Cardona-Morell and colleagues performed a systematic review of decision aids to help older patients facing serious illness and found 17 relevant studies (6 RCTs and 11 observational studies).(1) Compared to usual care, satisfaction with or acceptability of the decision process or the decision made was high regardless of the type of decision aid. The review also demonstrated that decision aids increased patient knowledge (but the improvement was small and absent in many trials), reduced decision conflict (but not consistently in all studies), and in a few trials, improved decision concordance between patients and their surrogates after exposure to a decision aid. In five studies, the decision aids included a values clarification process but only one made the trade-offs inherent in values clarification explicit. None explicated the difference between resuscitative/intensive care versus medical care versus comfort care. Together, these results suggest that the published decision aids to date may be lacking in their ability to help with the types of decisions that are most relevant to older individuals with serious illness.

Accordingly, we set out to develop a novel decision aid to support older patients prepare for serious illness. In developing the decision aid, we were considerate of the domains and items of International Patient Decision Aid Standards (IPDAS) instrument used to assess quality of decision support tools. (2)To develop the content of the decision aid, we first reviewed the literature on medical decision-making in the context of serious illness and drafted a preliminary version of the decision support intervention. We then created a "Goals of Care Designation (GCD) Clinic" in a family medicine primary care setting in Lethbridge, Alberta, Canada. In Alberta, a province-wide standard medical order form is used for

physicians to indicate the type of care a patient is to receive when seriously ill (resuscitative (intensive) care, medical care, or comfort care). It is the expectation of the health care system that all citizens of the province will meet with physicians to have this formed filled out in advance and will carry this form in an associated 'green sleeve' to their doctors' appointments or hospital visits. A family physician (AB) referred older patients with serious illness she expected would benefit from more in depth GCD discussions to this consultation clinic. DKH and RH met with patients to explain the context of the meeting, the decision to be made, and the various treatment options. Twenty-four patients were referred to the GCD primary care clinic and participated in the development phase of the decision aid. A description of their baseline demographic is found in eTable 1. The average age of participants was 78 years old, 37% were male, and most were in good health.

During these consultations, there were several key learnings that lead to further refinement of the decision support intervention. First, we realized that patients were having difficulty discriminating between planning for terminal care compared to planning for medical care when seriously ill. In our observations, the majority of patients just wanted to be kept comfortable when it was certain they were dying (condition of certainty). One of our concerns is that, to the extent that these patients misunderstood the context of the question about serious illness, they could be expressing a treatment preference that would result in their certain death when they could have recovered with simple curative treatments or intensive care, when appropriate. Accordingly, we created language strategies to help people understand the differences between terminal care and serious illness. However, when we explained that we were planning for serious illness where there was a probability of death but also, a probability that they may survive, they further struggled to express a treatment preference without knowing what the clinical outcome would be (condition of uncertainty). This required us to develop additional materials to explicitly define serious illness and the outcomes associated with it and to explain that the goal of the discussion was to express a preference that

would best capture the person's wishes at the present time, under conditions of 'uncertainty' about whether a sudden serious illness requiring hospitalization would be terminal or not. We likened this to listening to a weather report from a meteorologist where there is a certain probability of rain and, without knowing for sure whether it would rain or not, the person still had to decide whether they would go out and whether to bring an umbrella.

Second, we further observed that patients had difficulty expressing their values in a way that informed future medical decisions. Since the treatment options are preference sensitive and preferences should be aligned with values, we then developed a short values clarification tool that included an explanation of values and their relationship to treatment decisions and gave examples of different end-of-life (EOL) values (adapted from Scheunemann et. al. (3)). We further explained how certain values compete or conflict with each other, and patients were asked to rate on 7-point Likert-type scales 1) the degree to which quality of life was more or less important to them compared to quantity of life and 2) whether a natural death vs. a machine-supported death was more important (see eFigure 1 for examples of these scales). To aid in clinical decision-making and to make the linkage between values and preferences more explicit, we developed a system of grids that used the ratings of importance on the values questions to indicate which treatment option may be preferred (see eFigure 2). These treatment options were then described in more detail with information about the nature, location, harms, benefits and associated outcomes of the different treatment options provided in text and with visual images. Once the benefits and risks or harms of intensive care were explained, another set of value statements and associated grids was presented. Patients were then asked to rate their willingness to accept the risks of ICU care and their willingness to remain alive but in a potentially reduced health or functional state (See eFigure 1). The highlighted treatment options on the grid were not considered the definitive answer but rather, the grids were used to provide structured guidance to the patient helping them link their stated values to reasonable

treatment preferences. Where there were discordant treatment preferences highlighted on the grids (for example, the first grid suggested the preferred medical option was comfort care and the second grid indicated medical care), it led to a deeper conversation about why the discordance existed, the patient's values, and which values were most important, were further clarified. The final step of this consultation was to elicit a treatment preference for the use of life-sustaining treatments. To do so, we used a taxonomy describing different levels of the use or non-use of life-sustaining treatments (eTable 2 in supplementary appendix). This taxonomy was developed with input from medical experts and has been used extensively in our prior research.(4,5,6)Based on responses to values and initial grids (preferences), it was determined whether CPR is relevant and if so, patients watched a brief CPR video decision aid that is publicly available in the Plan Well guide Website. For patients preferring comfort care, this step was skipped.

Finally, to enable communication between the patient/facilitator interaction and the referring physician, we developed a standardized "Dear Doctor" letter that records the nature of the conversation, the stated values and expressed treatment preferences (See eFigure 3). This letter gave patients a written record of their 'talking points' with the doctor and our hypothesis was that this 'informed and capacitated' patient would be able to significantly influence medical decision-making to ensure that their stated treatment preferences are formally recorded on the goals of care documents and that the care they actually receive is more likely to be consistent with their authentic value structure.

When a near-final version of the decision support intervention was ready, we created a PowerPoint presentation that included all the content of the decision aid. We then held a series of focus groups and one-on-one interviews with 42 health care professionals with expertise in critical care medicine, nursing, geriatrics, family medicine, and palliative care, to obtain their input on the decision aid. The majority of the input focused on expanding the range of possible outcomes associated with intensive care treatments; hence, more information is presented on intensive care relative to medical and comfort care. Further

revisions were made and then the tool was evaluated by a group of lay patient and family advisors in Ontario and Alberta. We recruited 18 lay persons to participate in 2 hour face-to-face session in Kingston Ontario or a 2 hour webinar where the intervention was presented and a formal evaluation sought from participants. This evaluation instrument used in this project was informed by the framework for evaluation of sensibility developed by Feinstein (7) and adapted questions from a variety of other sources that have measured similar constructs.(8,9). In essence, we asked participants the questions with associated response options in eTable 3. The development and evaluation process is visually represented by eFigure 3.

Eighteen lay people participated in the final evaluation. Overall, on a scale of 1=poor and 5=very good, participants rated the tool a median of 5 (range 3-5). The majority found the language clear and understandable, was easy to work through, felt the amount of information was "just right", and thought the decision support tool would be very helpful to patients with serious illness. When asked if they would use it if recommended by their doctor, the median response was "definitely would use it." In addition, the majority also responded that they would recommend it to others (see eTable 3).

Supplemental Table S1. Demographic Information on Participants in Development Phase	
	n=24
Age	78.3±10.5 (53-94)
Sex	
Male	9 (37.5%)
Marital Status	
Married or living as married	14 (58.3%)
Widowed	8 (33.3%)
Never Married	1 (4.2%)
Divorced or separated; not remarried	1 (4.2%)
Where you been living in the past month	
Own home	20 (83.3%)
Retirement residence	4 (16.7%)
Highest level of education received	
University degree	2 (8.3%)
Some university or completed community college; technical college or post-secondary program	12 (50%)
Completed secondary/high school	6 (25%)
Did not complete secondary school or high school	4 (16.7%)
Language spoken daily	
English	24 (100%)
Rated Quality of life	
Excellent	1 (4.2%)
Very Good	11 (45.8%)
Good	10 (41.7%)
Fair	2 (8.3%)
Comorbidities	
Heart disease	14 (58.3%)
High BP	17 (70.8%)
Lung Disease	2 (8.3%)
Diabetes	8 (33.3%)
Ulcer or stomach disease	2 (8.3%)
Kidney disease	6 (25%)
Liver disease	0 (0%)
Anemia or other blood disease	3 (12.5%)
Cancer	2 (8.3%)
Depression	4 (16.7%)
Osteoarthritis, degenerative arthritis	10 (41.7%)
Back pain	8 (33.3%)
Rheumatoid Arthritis	1 (4.2%)
Level of Fitness and Frailty	
Very Fit	2 (8.3%)
Well	6 (25%)
Managing Well	11 (45.8%)
Vulnerable	4 (16.7)
Mildly Frail	1 (4.2%)

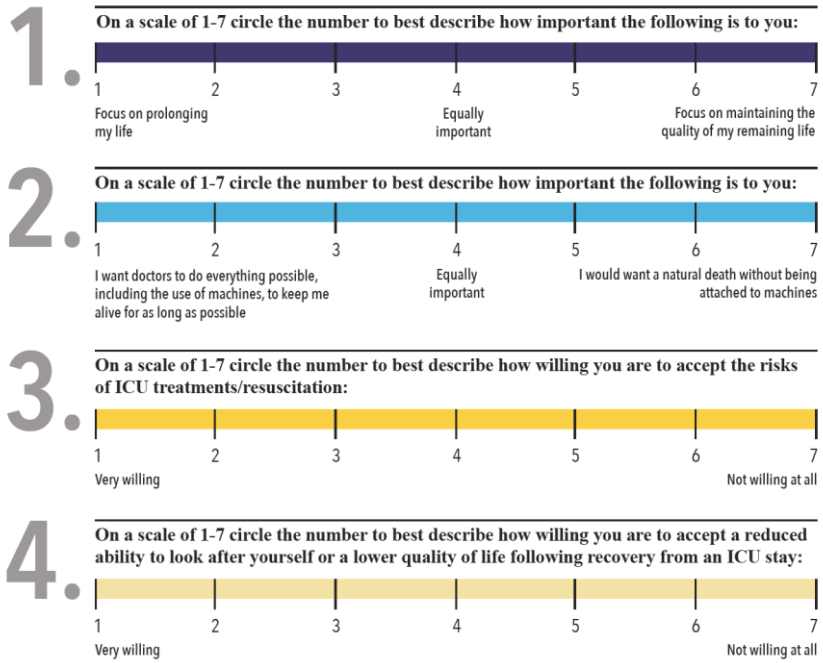
Appendix to: Heyland DK, Heyland R, Bailey A, et al. A novel decision aid to help plan for serious illness: a multisite randomized trial. *CMAJ Open* 2020. DOI:10.9778/cmajo.20190179. Copyright © 2020 Joule Inc. or its licensors

Supplemental Table S2. Method for Eliciting Treatment Preferences in the Context of Serious Illness	
At this point in time, if life supports were needed to keep you alive, which option would you prefer for your care? Please choose (√) one.	
❑	Use machines and all possible measures including resuscitation (CPR) with a focus on keeping me alive at all costs.
❑	Use machines and all possible measures with a focus on keeping me alive but if my heart stops, no resuscitation (CPR).
❑	Use machines only in the short term to see if I will get better but if the illness is prolonged, change focus to comfort measures only. If my heart stops, no resuscitation (CPR).
❑	Use full medical care to prolong my life but if my heart or my breathing stops, no resuscitation (CPR) or breathing machines.
❑	Use comfort measures only with a focus on improving my quality of life and comfort. Allow natural death and no artificial prolongation of life and no resuscitation (CPR).
❑	Unsure

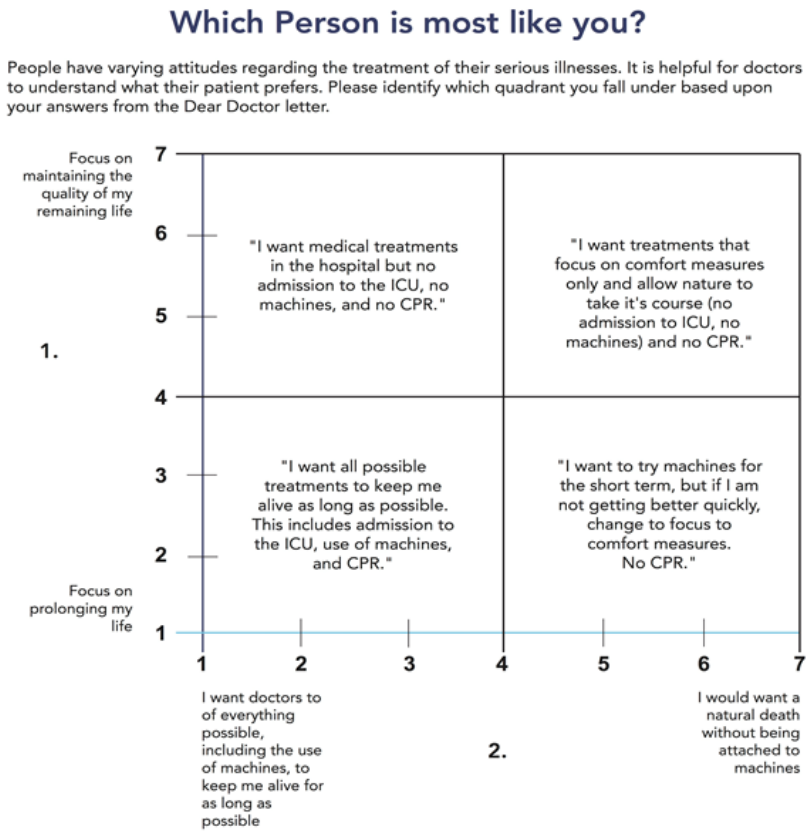
Supplemental Table S3. Results of Evaluation Phase (n=18 Lay Persons)		
Question	Median	Range
How would you rate the language used in the tool? (1 – Very Unclear, 5 – Very Clear)	4	1-5
The amount of information in the tool was: (1 – Much less, 3- about right, 5 – Much more)	3	2-3
Overall, how difficult or easy was it to work through the tool? (1 – Very difficult, 5 – Very easy)	4	3-5
How helpful would this tool be for a patient who is thinking about medical treatment for a serious illness? (1 – Very Unhelpful, 5 – Very Helpful)	5	3-5
How likely would you be to use this tool if your doctor recommended it? (1 – Definitely would not, 5 – Definitely would)	5	3-5
How likely would you be to recommend this tool to someone else for the purpose of discussing options for medical treatment of a serious illness? (1 – Definitely would not, 5 – Definitely would)	5	3-5
Overall, how would you rate the tool? (1 – Very Poor, 5 – Very Good)	5	3-5

 Copyright © 2020 Joule Inc. or its licensors

Supplemental Figure S1. Constrained Values Scales

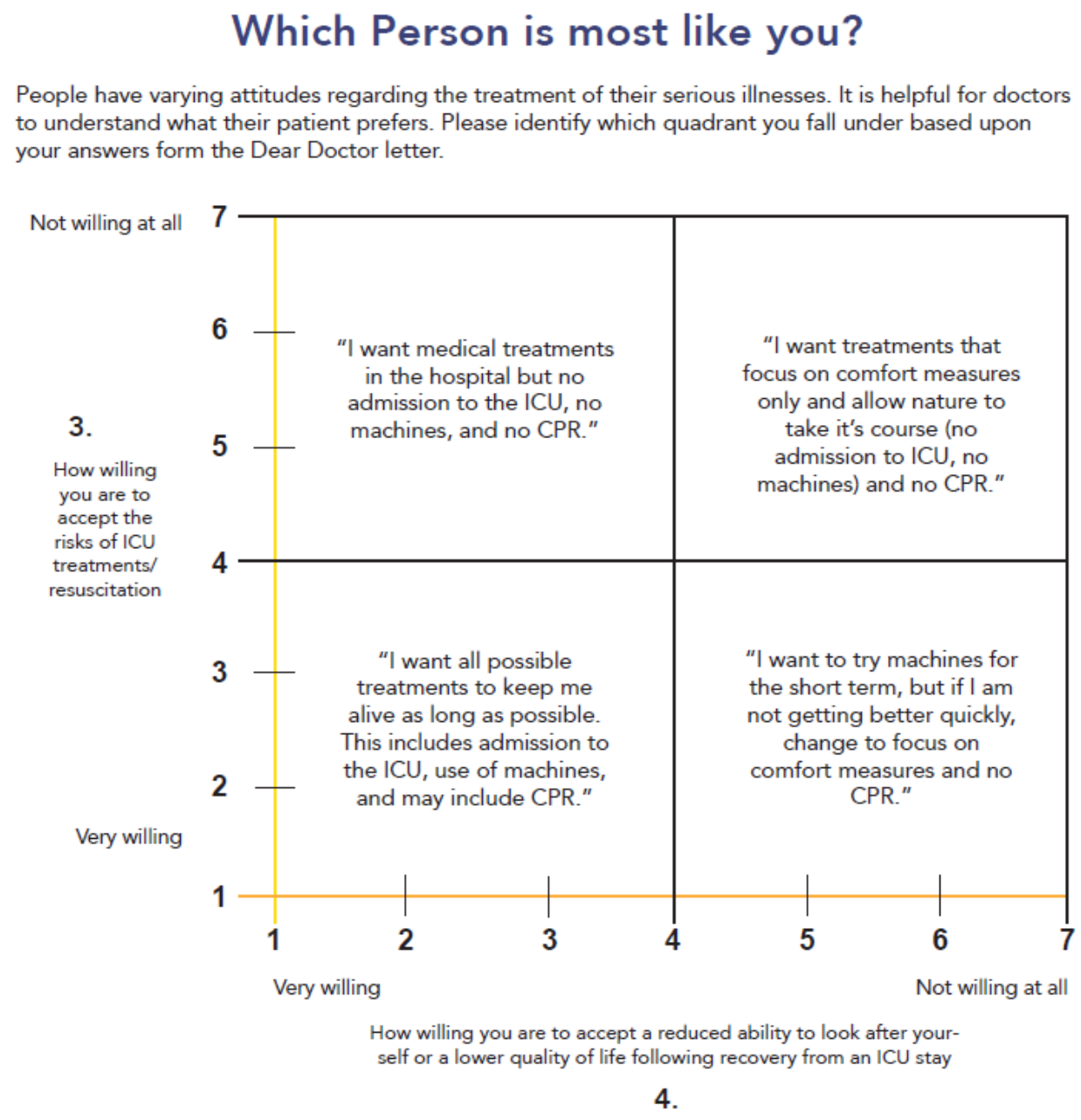


Supplemental Figure S2. Grid Indicating Relationship Between Values and Treatment Preferences A)



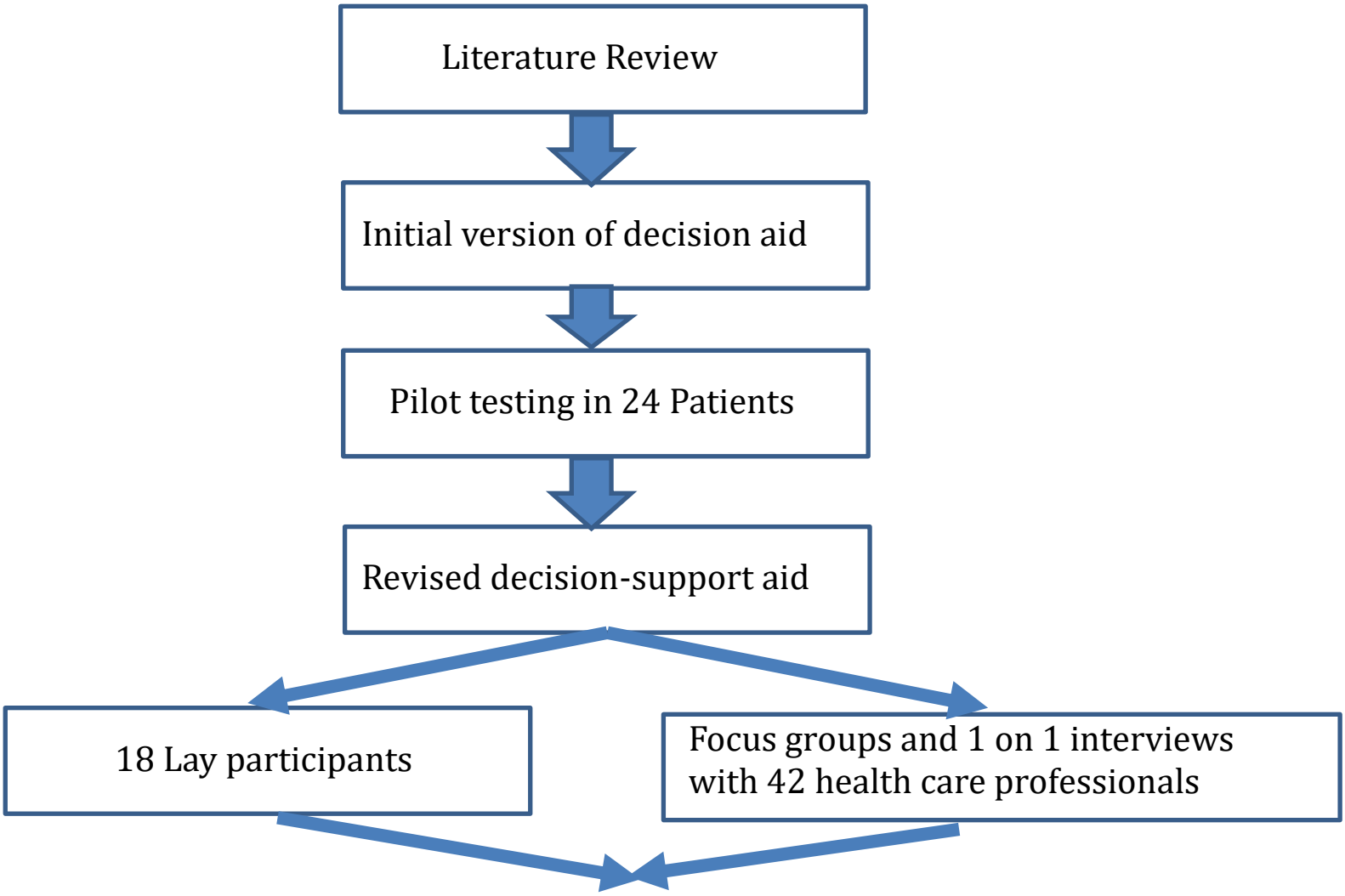
Appendix to: Heyland DK, Heyland R, Bailey A, et al. A novel decision aid to help plan for serious illness: a multisite randomized trial. *CMAJ Open* 2020. DOI:10.9778/cmajo.20190179. Copyright © 2020 Joule Inc. or its licensors

B)



Appendix to: Heyland DK, Heyland R, Bailey A, et al. A novel decision aid to help plan for serious illness: a multisite randomized trial. *CMAJ Open* 2020. DOI:10.9778/cmajo.20190179. Copyright © 2020 Joule Inc. or its licensors

Supplemental Figure S3: Plan Well Guide™ Development and Evaluation Schema



Appendix to: Heyland DK, Heyland R, Bailey A, et al. A novel decision aid to help plan for serious illness: a multisite randomized trial. *CMAJ Open* 2020. DOI:10.9778/cmajo.20190179. Copyright © 2020 Joule Inc. or its licensors

REFERENCES

1. Cardona-Morrell M, Benfatti-Olivato G, Jansen J, Turner RM, Fajardo-Pulido D, Hillman K. A systematic review of effectiveness of decision aids to assist older patients at the end of life. Patient Educ and Couns. 2017;100;425-435.

2. Elwyn G, O'Connor AM, Bennett C, Newcombe RG, Politi M, Durand MA, et al. Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi). PLoS One. 2009;4;e4705.

3. Scheunemann LP, Arnold RM, White DB. The facilitated values history: helping surrogates make authentic decisions for incapacitated patients with advanced illness. Am J Respir Crit Care Med. 2012;186;480-486.

4. Heyland DK, Dodek P, Mehta S, Cook D, Garland A, Stelfox HT, et al; Canadian Critical Care Trials Group and Canadian Researchers at End of Life Network (CARENET). Admission of the very elderly to the intensive care unit: family members' perspectives on clinical decision-making from a multicenter cohort study. Palliat Med. 2015; 29;324-335.

5. You JJ, Downar J, Fowler RA, Lamontagne F, Ma IW, Jayaraman D, Kryworuchko Jet al; for the Canadian Researchers at the End of Life Network (CARENET). Barriers to goals of care discussions with seriously ill hospitalized patients and their families: A multicenter survey of clinicians. JAMA Intern Med. 2015;175;549-556.

6. Heyland DK, Frank C, Groll, D, Pichora D, Dodek P, Rocker G, Gafni A for the Canadian Researchers at the End of Life Network (CARENET). Understanding cardiopulmonary resuscitation decision making: Perspectives of seriously ill hospitalized patients and family members. Chest. 2006;130(2):419-428.

7. Feinstein AR. The theory and evaluation of sensibility. In: Feinstein AR, editor. Clinimetrics. Westford, MS: Murray Printing Company; 1987. pp 141-166.

8. Barry MJ, Fowler FJ, Mulley Jr. AG, Henderson JV, Wennberg JE. Patient reactions to a program designed to facilitate patient participation in treatment decisions for benign prostatic hyperplasia. MedCare. 1995;33;771-782.

9. O'Connor AM, Cranney A. User Manual – Acceptability [document on the Internet]. Ottawa: Ottawa Hospital Research Institute; ©1996 [modified 2002; cited 2014/12/03]. 5 p. Available from http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Acceptability.pdf