# Evidence-based Practice Center
Technical Brief Protocol
Project Title: Decision Aids for Advanced Care Planning

I. Background and Objectives for the Technical Brief

Advanced care planning (ACP) for end-of-life decision making is a process of planning for the future. Such planning may be triggered by estate planning or because of medical illness. Advanced care planning involves learning about potential impending decisions, considering those decisions in advance and identifying preferences, and letting others know those preferences, often by recording them in an advanced directive. Decisions to consider during ACP are largely driven by the individual's health state at the time of planning. Figure 1 illustrates a health state continuum with several common health states that trigger ACP activities. Healthy people engaged in estate planning may consider common decisions that arise near death, such as cardiopulmonary resuscitation, ventilator use, artificial nutrition/hydration, and hospice or comfort care. Some individuals may face additional decisions related to their specific health conditions or diseases. As one moves to the right of the spectrum, the immediacy of the need for ACP increases.

Figure 1. Continuum of health states during which ACP may be considered
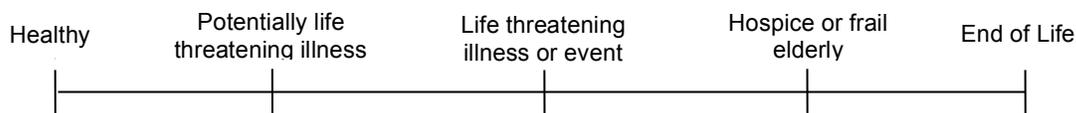
ACP is a process intended to ensure that patients receive the care they want near the end of life. Several issues interfere with achieving this goal. Just because ACP is made available does not mean it will be undertaken, or if undertaken, that it will effectively guide decisionmaking. An even more fundamental challenge, however, is that the ACP process assumes that people can imagine themselves or their loved ones in a future health state. Healthy people, or people still early in a disease process, may have more difficulty with doing this than people in more advanced stages of illness. When people cannot fully imagine a future health state, the ACP process may be ineffective. Such patients and/or their proxies may have structured discussions with their providers and identify preferences for future medical care. But if those stated preferences are based on an incomplete understanding of how the future health state will actually feel, the patient may discover that his or her preferences are quite different when end-of-life care is actually needed. Decision aids, by creating a structured approach to considering options, probabilities, and/or the realities of health states, are one approach to improve the knowledge base for a patient/proxy. A better knowledge base can potentially improve a patient's ability to more accurately imagine potential future health states, and thus improve their participation in the ACP process.

Tools for ACP involve many methods, including: legal standard paragraphs for statements of preferences, durable power of attorney, values-based health care directive templates, intervention-focused health care directives templates, physician orders for life sustaining treatments, disease-specific health advance care planning information/education, disability-level focused health care directive templates, facilitated discussions of preferences, group classes, videos, pamphlets, and interactive computer programs. Yet, not all tools for ACP qualify as decision aids. We may be tempted to think of educational videos and pamphlets as decision aids because they serve to inform people about choices. However, ACP tools and templates generally support an individual in thinking through the decision processes and prompt the individual to take a concrete action about ACP.

There is considerable diversity in the populations that may be involved in ACP, and in the formats of existing decision aids, yet the empirical literature supporting decision aids for ACP is sparse. This Technical Brief will present the "lay of the land" and describe existing decision aids for ACP. We will provide a framework to help readers when considering which decision aid may best fit their particular environment or need. Thus, the Brief will focus on the decision aids themselves and the context within which they are used. It will not focus on the ACP decisionmaking process for patients. Because of the complexity inherent to ACP for diverse populations with widely varying health states, and thus also the decision aids that support ACP, the Brief is focused on ACP for adult populations. Therefore, we will exclude pediatric populations. The contexts in which parents of gravely ill children must make decisions differ qualitatively from decisionmaking contexts for adult patients. Further, children as legal minors must rely on their parents to make decisions for them—and they may not reach the age of majority and thus the ability to form their own legally binding decisions.

We define decision aids broadly as a form or a tool that includes some form of behavioral prompt. We use the International Patient Decision Aid Standards instrument criteria[1,2] of an education component, a structured approach to thinking about the choices a patient faces, and a way for those choices to be communicated. The choices being considered may be specific therapy choices, including taking no action, or the clarification of values. Since ACP is often not undertaken in clinical settings, and since the partners in shared decisionmaking processes may be other family members or caregivers rather than clinicians, the decision aid should include some prompt the patient to record the decisions for the time when the person is no longer capable of communicating them, or explicit instructions for the person to communicate his values, preferences, or decisions to the chosen proxy.

For the purposes of this report, advance care planning is defined as learning about the types of decisions that might need to be made, considering those decisions ahead of time, and then letting others know about your preferences, often by putting them into an advance directive. This could include choosing a proxy, making sure your proxy knows your preferences, and documenting your proxy through a durable power of attorney.

II. Guiding Questions

1. What decision aids for ACP have been proposed or used in practice?
   a. What are the characteristics of the decision aid, such as the goal, mode of delivery, and settings in which it is used?
   b. How well do the decision aids meet decision aid criteria?
2. In what contexts are decision aids for ACP currently used, and what are the limitations of their use?
   a. Who generally facilitates the ACP decision process in which the decision aid is used?
   b. How are the decisions generated by the decision aid documented?
   c. How are the decision aid and/or its documentation transferred/communicated to health care settings where the healthcare activities take place?
   d. What are the implications of the combination of the health state of the person completing the decision aid, the setting in which the decision aid is completed, and whether the decisions are hypothetical or concrete?
   e. What is the legal environment and requirements for ACP for which the decision aids are used?
3. What is the current evidence for decision aids for ACP?
   a. What decision aids have been studied for effectiveness?
   b. What are the inclusion and exclusion criteria of people in studies of the effectiveness of decision aids?
   c. What were the settings examined?
   d. What outcomes were examined?
   e. Were harms or adverse effects collected in the studies; what were they?
   f. What comparators were used to examine benefits and harms?
4. What are the important issues raised by decision aids for ACP and how they are used?
   a. What are the ethical considerations regarding using decision aids for ACP?
   b. How are people guided in choosing healthcare proxies?
   c. What are the implications of legal versus healthcare settings for ACP; do the decision aids adequately address the related concerns?
   d. What are possible areas of future research?

III. Methods

We will integrate the information from the Key Informants and a systematic literature review into a single, cohesive review process. In particular, responses to guiding questions 1, 2, and 4 will rely on information from Key Informants and published information about decision aids and the context within which they are used. Responses to question 3 will be based on peer-reviewed, published studies that examined outcomes after the use of decision aids.

1. Data Collection.

A. Discussion with Key Informants.

We will identify relevant Key Informants for this technical brief, ensuring both balanced viewpoints and efficient data collection. We will include experts in the development and use of decision aids and ACP. We will also include estate attorneys and clinicians who may use decision aids when engaging in facilitating ACP, representatives of organizations involved in medicine, nursing, social work, and hospital/nursing home care who may be involved either in facilitating use of the decision aid or interpreting the completed documentation. We will also include representatives of clergy, bioethicists, and medical law.

We will locate potential Key Informants from frequently listed and cited authors of relevant literature, internet searches for possible candidates of relevant viewpoints, and nominations by other Key Informants. In cases where the Minnesota EPC is not able to identify a specific individual to represent a specific organization, we will invite the organization to nominate an individual. In cases where a Key Informant has a potential conflict of interest but is still deemed to have a viewpoint or specific expertise critical to the brief, we will interview the individual separately from other Key Informants to avoid undue influence.

We will conduct semi-structured interviews with the Key Informants to gather information on their opinions regarding decision aids for ACP. Below are examples of the types of questions that will be used in the Key Informant discussions. The Key Informants will receive invitation letters which will provide a brief description of the project and the Key Informant's expected role, and appropriate disclosure forms for conflict of interest. Experts in the field will be convened separately from clinicians and advocates. We will assign Key Informants to conference calls to balance maximizing the synergy of group discussions and minimizing unhelpful conflict. Summaries of calls will be circulated to participants for content confirmation.

Questions for experts/researchers/provider organizations/practicing clinicians
   a. What decision aids do you use in advanced care planning?
   b. What specific ACP tools and aids characterize your program? (May we see them?)
   c. What do you see as the strengths and weaknesses of the decision aids you have used? The barriers and facilitators of using the decision aids?
   d. Grey literature: which professional organizations are important to consult regarding:
      i. Tools
      ii. Preliminary study findings
   e. Review/comment on definitions of ACP and decision aid models
   f. What types of research are needed most? What outcomes? What designs? When should outcomes be measured (length of followup)?
   g. What format works best in your experience?

h. Which health care directive form do you prefer?

Questions for patient advocates, families, caregivers
   a. What information do patients need to know when planning advanced care?
   b. Does that information change based on your level of health?
   c. What do you view as the advantages/disadvantages of advance planning?
   d. How did the decision aid help with the planning process?

Questions for ethicists/clergy/law
   a. What do you consider important ethical considerations that need to be addressed with regard to ACP and decision aids?
   b. How do decision aids help or change the dynamics of the ACP process itself, and, if conducted as a dialogue, discussions between patients, family members, and providers?
   c. What information do you believe is most needed by people considering ACP?
   d. What kinds of research would be most useful? What outcomes?
   e. To what extent should the health care professional facilitating the conversation give advice (person as decision aid)?

B. Grey Literature search.

To identify decision aids currently in use, we will conduct a grey literature search of federal and state government websites, the Ottawa Hospital Research Institute's Decision Aid Library Inventory (DALI), professional organizations, and leads from KInformants. We will also use internet search engines such as Google to find information on decision aids for ACP as well as on issues and controversies regarding their use. We will survey enrolling and ongoing clinical trials though ClinicalTrials.gov, HSRProj, and NIH RePORTER databases, and the PCORI website. We will search the LexisNexis database for current discussions of legal/ethical considerations and controversies.

C. Published Literature search.

We will search several databases: MEDLINE® via OVID, the Cochrane Library, PsychINFO, and CINAHL database. Exact search strategies have been developed in consultation with the EPC librarian. We have developed an *a priori* search strategy based on relevant medical subject headings (MeSH) terms and text words. The search string is provided in Appendix 1. The Key Informants may suggest additional sources of evidence.

We will screen the resulting literature for published articles of empirical research that are relevant to the guiding questions. For Guiding Question 3, we will search for eligible studies that examined the use of decision aids for advanced care planning. We will include studies published in English of any sample size and any design (randomized controlled trial, controlled clinical trial, uncontrolled observational trial, and case reports and series). We will exclude studies that focus on implementation science questions. Further inclusion/exclusion criteria are provided in Table 1.

Table 1. Inclusion/Exclusion criteria by PICOTS

Element	Included	Excluded
Population	Any adult potential patient, whether general or identified by disease	Pediatric patients, Non-US populations
Interventions	Decision aids for future health states that include a behavioral prompt	• Religious or other edicts that specify what decision a patient should make (e.g. "artificial nutrition must be accepted" or "blood transfusions may not be accepted") • An attorney's standard paragraph about preferences inserted into a health care directive, that does not provide information about risks, benefits or alternatives • A simple form that names a health care proxy (without providing a list of powers to choose from that would be afforded to the proxy) • Health care providers' verbal recommendations • Educational materials and research publications intended for health care professionals to help them give verbal recommendations to patients • Educational materials that only promote the process of advance care planning, without providing information to help individuals make the decisions that are part of ACP • Statutes, government policies, and health care institutional policy and procedure that describe and promote ACP or specify decision aids that must be used • Advanced planning for psychiatric care; decisions about treatment for a disease, not end of life decisions
Comparators	No aid, "traditional care," education-only material	
Outcomes	Decision agreement, confidence, patient satisfaction, knowledge, comfort, uptake. May be either patient or family/caregiver	Implementation or process measures
Timing	Decisions made for future health states	End of life decisions for current health states
Settings	Decision aids used for health care or legal settings, whether in the presence of an attorney or do-it-yourself websites	

2. Data organization and presentation.

A. Information Management.

We will abstract data from the published literature using the standardized data abstraction tools shown in Appendix 2. One reviewer will collect the data and assess the evidence against the inclusion and exclusion criteria. We will not abstract actual results from the studies.

Data from the published literature will be integrated with information from the grey literature and discussions with Key Informants. Responses to Questions 1 and 2 will be formed with information from published narrative reviews, information in the grey literature, and Key Informant discussions. Responses to Question 3 will be based primarily on peer-reviewed, published literature and may be combined with information gleaned from the grey literature (e.g. information from on-going studies). Responses to Question 4 will be formed by Key Informant discussions along with information used to address Questions 1 – 3.

B. Data Presentation.

The data will be presented in narrative form (Q1, 2, and 4) and in evidence tables. We will summarize the evidence into summary tables/plots by decision aid and its use. Possible summary tables are provided in Appendix 2. The tables are organized to provide descriptive details of identified decision aids and their conformance to decision aids criteria. For the criteria, we will modify the International Patient Decision Aid Standards instrument[2] to accommodate the hypothetical nature of the decisions under consideration and the possibility of the decision aids being used without the presence of a clinician. We will review the tables throughout the Key Informant discussions and literature searches to assess whether the tables are adequately capturing important relevant concepts.

IV. References

1. O'Connor AM, Stacey D, Entwistle V, Llewellyn-Thomas H, Rovner D, et al. The Cochrane Library., Chichester, UK: John Wiley&Sons, Ltd; 2004. Decision aids for people facing health treatment or screening decisions (Cochrane Review) Issue 1.
2. Elwyn G, O'Connor AM, Bennett C, Newcombe RG, et al. Assessing the quality of decision support technologies using the international patient decision aid standards instrument (IPDASi). PLoS One. 2009; 4(3): e4705 PMCID: PMIC2649534

V. Definition of Terms

Not applicable

VI. Summary of Protocol Amendments

VII. Key Informants

Within the Technical Brief process, Key Informants serve as a resource to offer insight into the clinical context of the technology/intervention, how it works, how it is currently used or might be used, and which features may be important from a patient of policy standpoint. They may include clinical experts, patients, manufacturers, researchers, payers, or other perspectives, depending on the technology/intervention in question. Differing viewpoints are expected, and all statements are crosschecked against available literature and statements from other Key Informants. Information gained from Key Informant interviews is identified as such in the report. Key

Informants do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

VIII. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

Appendix 1.

Preliminary literature search. We will search MEDLINE using the algorithm listed below. We will adjust the algorithm to also search the Cochrane Library, PsychINFO, and CINAHL databases.

Database: Ovid MEDLINE(R) <1946 to August Week 4 2013> Search Strategy:
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1   exp Advance Care Planning/ (6874)
2   exp Advance Directives/ (6012)
3   "advanced care plan*".ti. (16)
4   "advance* care plan*".m_titl. (373)
5   (advance* adj2 directive*).ti. (1466)
6   "living will*".m_titl. (534)
7   "end of life".mp. (10604)
8   exp Decision Support Techniques/ (61793)
9   exp Decision Support Systems, Clinical/ (5097)
10   decision aid*.mp. (1298)
11   decision tool*.mp. (339)
12   decision support.mp. (20794)
13   instrument*.ti,ab. (168622)
14   intervention*.ti,ab. (512195)
15   program*.ti,ab. (534141)
16   exp *Decision Making/ (53054)
17   12 or 13 or 14 (1126467)
18   15 and 16 (6792)
19   7 or 8 or 9 or 10 or 11 or 17 (77632)
20   1 or 2 or 3 or 4 or 5 or 6 (16119)
21   19 and 20 (340)

Appendix 2. Proposed summary tables

Table 1. Decision aids framework

	Caregiver involvement	Help Choosing Proxy	Decisional Capacity	ACP Facilitator (formal training)	Depth of Relationship
Healthy					
Potentially Life Threatening					
Life Threatening					
Hospice/Frail Elderly					

Table 1. Decision aids framework

	Structured Decision Options	Evidence for Options	Treatment choices when not curable	Life-prolonging treatment or comfort care	ACP Settings
Healthy					
Potentially Life Threatening					
Life Threatening					
Hospice/Frail Elderly					

Table 2. List of decision aids available

Decision Aid/ Use	Developer	Type/Setting	Delivery Mode	Goal (document/discussion space)	Number of studies that tested the decision aid(references)

Table 2 cont. List of decision aids available

Decision Aid/ Use	Valid as order to EMS	Disease Specific	Languages	Format (multiple choice/free text)	State law described/ prescribed/ neither

Note: Table one may be expanded or retracted based on final set of attributes arrived at through conversations with Key Informants.

Table 3 Criteria covered by decision aid (based on IPDASC) – content and effectiveness

Decision Aid/ Use	Provide Information	Present probabilities	Clarify patient values	Structure guidance	Informed and values based

Table 3 cont (Development process (additional categories if internet based or vignettes used)

Decision Aid/Use	Balanced Manner	Systematic development	Scientific evidence	COI	Plain language

Table 4. Studies that examined decision aids in different populations (possibly by study design)

Decision Aid/Use	Clinical population/ General	Inclusion criteria-	Exclusion criteria	Sample size/Study design	Comparator	Harms (ethical/ emotional harms)

Table 4. Possible outcomes examined in decision aid research

Decision Aid/Use	Decision agreement	Confidence	Patient Satisfaction	Uptake	Knowledge	Comfort