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Review

Tools to Promote Shared Decision Making in Serious Illness

A Systematic Review

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IMPORTANCE Serious illness impairs function and threatens survival. Patients facing serious illness value shared decision making, yet few decision aids address the needs of this population.

OBJECTIVE To perform a systematic review of evidence about decision aids and other exportable tools that promote shared decision making in serious illness, thereby (1) identifying tools relevant to the treatment decisions of seriously ill patients and their caregivers, (2) evaluating the quality of evidence for these tools, and (3) summarizing their effect on outcomes and accessibility for clinicians.

EVIDENCE REVIEW We searched PubMed, CINAHL, and PsychInfo from January 1, 1995, through October 31, 2014, and identified additional studies from reference lists and other systematic reviews. Clinical trials with random or nonrandom controls were included if they tested print, video, or web-based tools for advance care planning (ACP) or decision aids for serious illness. We extracted data on the study population, design, results, and risk for bias using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) criteria. Each tool was evaluated for its effect on patient outcomes and accessibility.

FINDINGS Seventeen randomized clinical trials tested decision tools in serious illness. Nearly all the trials were of moderate or high quality and showed that decision tools improve patient knowledge and awareness of treatment choices. The available tools address ACP, palliative care and goals of care communication, feeding options in dementia, lung transplant in cystic fibrosis, and truth telling in terminal cancer. Five randomized clinical trials provided further evidence that decision tools improve ACP documentation, clinical decisions, and treatment received.

CONCLUSIONS AND RELEVANCE Clinicians can access and use evidence-based tools to engage seriously ill patients in shared decision making. This field of research is in an early stage; future research is needed to develop novel decision aids for other serious diagnoses and key decisions. Health care delivery organizations should prioritize the use of currently available tools that are evidence based and effective.

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Serious illness raises the stakes for engaging patients and families in health care decisions.¹⁻³ Patients with serious illness include those with critical life-threatening illness, advanced stages of major chronic diseases, or multimorbidity and frailty. They confront debilitating symptoms and impending threats to function, decisional capacity, and survival. Patients, caregivers, and health care practitioners identify communication and shared decision making as essential components of good care in serious illness.² However, poor quality of communication between patients and practitioners limits the patients' knowledge of prognosis and treatment options, management of symptoms, and use of treatments consistent with their preferences.^{4,5}

Structured tools are a novel method to improve knowledge transfer and promote patient engagement in health care choices. Tools that use print, video, or web-based media are designed to share information about an illness and promote informed decisions about treatment. These tools are not a substitute for clinical communication, but are intended to prepare and empower patients and their families for shared decision making with clinicians. Some tools are designed to improve the patients' knowledge about clinical issues. Other tools are formal decision aids, which are more highly structured to address the risks and benefits of and alternatives to treatment and are designed to prepare patients for their role in key decisions.⁶ Randomized clinical trials (RCTs) have shown that decision aids improve the quality and efficiency of decision making, increase comprehension and decisional participation, and decrease decisional conflict.⁷ Despite the importance of shared decision making in serious illness, most formal decision aids have addressed the needs of healthier outpatients, and a recent Cochrane review excluded advance care planning (ACP) tools.⁸

No systematic review, to our knowledge, has synthesized the evidence for communication tools and decision aids in serious illness. We therefore sought to assess the quality and accessibility of decision aids and tools for ACP designed to empower and improve the care of patients with serious illness. To meet this objective, we conducted a systematic review of published clinical trials of decision aids and ACP tools to promote shared decision making in serious illness. The goals of this study are to (1) identify tools relevant to the needs of treatment decision making by seriously ill patients and their caregivers, (2) evaluate the quality of evidence for these tools, and (3) summarize their effect on patient-centered outcomes and accessibility of tools for clinicians.

Methods

Data Sources and Searches

We searched PubMed, CINAHL, and PsychInfo from January 1, 1995, through October 31, 2014, and identified additional studies from reference lists and relevant systematic reviews. Our electronic search strategy included the following terms using text word (tw) or MeSH field tags: (brochure*[tw] OR pamphlet*[tw] OR booklet*[tw] OR communication tool*[tw] OR DVD*[tw] OR multi-media[tw] OR multimedia[tw] OR Decision Aid*[tw] OR Internet[MeSH] OR website*[tw] OR web site*[tw] OR videotape recording[MeSH] OR videodisc recording[MeSH] OR video-audio media[publication type]) AND (terminal[tw] OR chronic[tw] OR advanced[tw] OR severity[tw] OR severe[tw] OR failure*[tw] OR end stage[tw] OR endstage[tw] OR

dying[tw] OR Intensive Care Units[MeSH] OR intensive care[tw] OR ICU[tw] OR hospice*[tw]) AND (Patient[MeSH] OR Patient[tw] OR patients[tw] OR family[MeSH] OR family[tw] OR families OR son[tw] OR sons[tw] OR daughter*[tw] OR parent[tw] OR parents[tw] OR spouse[tw] OR spouses[tw] OR husband*[tw] OR wife[tw] OR wives[tw] OR caregiver*[tw]).

Study Selection

This systematic review includes published nonrandomized clinical trials and RCTs that test decision tools intended for use by patients and their caregivers. Studies were included if they tested tools to improve treatment decision making for patients living with serious illness. Decision tools were included whether or not they met the International Patient Decision Aid Standards Collaboration definition for decision aids, that is, tools that present treatment options in a balanced and evidence-based manner.⁸ Tools were included if they were structured for use by the patient or family caregiver without immediate clinician support. For instance, we excluded interventions that required communication training for clinicians or extensive patient coaching. Formats included print, video, or web-based decision tools. Content had to be relevant for communication about major treatment decisions in serious illness. Included studies could be from any health care setting or country if they were written in English and amenable to quality analysis. Given the early stage of this field of research, we accepted randomized or nonrandomized controls and diverse outcomes and lengths of follow-up.

We defined an eligible patient population as adults living with advanced-stage or potentially life-limiting diseases, including critical illness, metastatic cancer, advanced stages of renal or liver disease, chronic obstructive pulmonary disease, cystic fibrosis, systolic congestive heart failure, human immunodeficiency virus infection and/or AIDS, or advanced neurodegenerative diseases, such as Parkinson disease, amyotrophic lateral sclerosis, or dementia. Studies were excluded if they addressed prevention or stable chronic disease at an early stage. Because communication and decision making differ greatly for children, we included only interventions for patients 18 years or older.

Two of us (D.M. and L.C.H.) reviewed all titles and abstracts and excluded abstracts that did not address patients with serious illness. Two of us (C.A.A. and L.C.H.) independently reviewed all the remaining abstracts and excluded observational studies, studies of patients with insufficient illness severity, or studies of nonexportable interventions. At least 2 of us then examined each full article of the remaining published studies to determine final inclusion and exclusion. Any disagreements were resolved by consensus discussion. Additional studies were accepted after hand searching reference lists of the included studies and asking content experts for additional suggestions.

Data Extraction and Quality Assessment

We created a standardized data extraction instrument to prepare evidence tables. This instrument followed the CONSORT criteria^{9,10} and the Transparent Reporting of Evaluations With Nonrandomized Designs (TREND) criteria.¹¹ Data extraction included study design and the type of control or comparison group; target population and severity of illness; primary and secondary outcome measures; reported results; and intervention type categorized as ACP for a future decision or support for a current clinical decision.

Data Synthesis and Analysis

Two of us (C.A.A. and L.C.H.) analyzed the studies' risk for bias based on the presence or absence of the following 8 elements: randomization with or without allocation concealed, blinding of outcome assessment, blinding of participants, specification of outcomes, specification of inclusion criteria, greater than 75% completion of outcome data, adjustment for confounding, and intention-to-treat analysis. Analysis followed the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) criteria used in Cochrane systematic reviews.^{12,13} Studies meeting 5 or more of these criteria were assessed as high quality (GRADE A) with a low risk for bias; those meeting 3 to 4 criteria, as intermediate quality (GRADE B) with a medium risk for bias; and those meeting 0 to 2 criteria, as lower quality (GRADE C) with a high risk for bias. To reduce bias in reporting, one of us (C.A.A.) led the review of studies authored by investigators conducting this systematic review. We used the PRISMA checklist to design and report the study.¹⁴

To summarize the potential clinical impact of each decision tool, we developed categories to describe the degree of change in patient-centered outcomes. Interventions that lead to improvement in patient outcomes of symptom distress, satisfaction, or quality of life or changes in treatment experiences were termed *high impact*. Tools with evidence of patient or caregiver behavioral changes or actual treatment choices were termed *moderate impact*. Tools with no effect on outcomes or those addressing intermediate outcomes, such as change in knowledge or attitudes, were termed *lesser impact*. To describe the accessibility of each tool, we searched the published studies and the Internet for information on how to view and use the tool and whether it was free or had to be purchased.

Results

Of the initial 9995 titles identified by the search strategy, 389 met our criteria for full abstract review, and 110 met our criteria for full text review. Seventy-five studies were excluded, and 3 additional titles were included from hand searching reference lists. In total, 38 articles met all inclusion criteria (Figure).

Seventeen of the included studies were RCTs, and the remaining 21 studies were trials with a small pilot or preintervention-postintervention study design. Six of the RCTs tested tools for ACP for future decisions, and 11 tested tools to support immediate treatment choices.

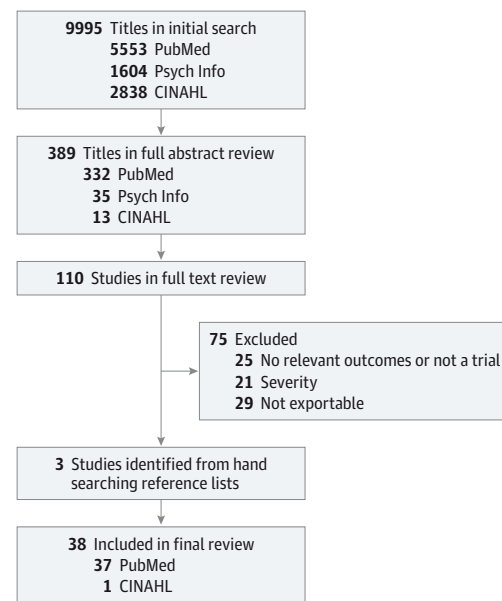
Small Pilot and Preintervention-Postintervention Studies

The 21 pilot studies^{7,15-34} were designed to examine feasibility and to provide preliminary evidence for newly developed decision tools (Table 1). Seven pilot trials tested ACP tools for future decisions,^{15,23-27,34} and 14 tested tools to support patient engagement in current decisions.^{7,16-22,28-33} Seven of the pilot trials^{15-19,21,22} have been followed by published RCTs,³⁵⁻⁴² and a search of trial registries revealed that 2 additional studies^{7,20} are being tested in clinical trials.

RCTs of Decision Tools for ACP

Six RCTs^{35-37,43-45} tested 4 different ACP tools, including a short video, a low-health-literacy print tool, a workbook, and a website. Within this group, nearly all studies were of high quality and targeted out-

Figure. Literature Search and Selection



patient populations (Table 2). All but 1 tool improved patient knowledge,^{35-37,43,44} and 2 tools had an effect on clinical decisions.^{43,44}

Three high-quality (GRADE A) clinical trials tested a 2-minute video developed by Volandes et al³⁵⁻³⁷ on features of advanced dementia to inform ACP discussions, should individuals develop this health condition. Each study tested the video in different outpatient populations. The largest of these 3 trials³⁵ enrolled 200 outpatients 65 years and older and found that viewing the video resulted in a significant increase in patients reporting that they would choose comfort as their primary goal for a future health state of advanced dementia (86% vs 64%; $P = .003$). Another study³⁷ examined 76 rural outpatients and demonstrated an increased choice of comfort as their primary goal for advanced dementia (91% vs 72%; $P < .001$). A third study of 14 outpatients older than 65 years³⁶ demonstrated increased concordance between patients and their surrogates after viewing the video (100% vs 33%; $P = .02$). These trials examined immediate preference change, but they did not examine outcomes such as documentation of preferences or discussion of preferences with health care practitioners.

The remaining 3 ACP studies⁴³⁻⁴⁵ tested the effect of 3 different tools on the expression and documentation of treatment preferences. One high-quality (GRADE A) RCT by Sudore et al⁴³ examined an advance directive that was modified for patients with lower health literacy and found it improved ease of use when compared with a standard advance directive document (69.1% vs 48.7%; $P < .001$). Six months later, those patients who used the literacy-adjusted advance directive were more likely to have completed a written directive (18.5% vs 7.7%; $P = .03$). The RCT by Pearlman et al⁴⁴ was of intermediate quality (GRADE B). The authors examined an ACP workbook and found a significant increase in the discussion of ACP with health care practitioners (64% vs 28%; $P < .001$) and in documentation of living wills (48% vs 23%; $P < .001$). Finally, a

Table 1. Small Pilot and Preintervention-Postintervention Studies

Source	Intervention and Study Population Description	Follow-up RCT
Decision Making Tools for ACP		
Braun et al, ²³ 2006	Booklets on 5 end-of-life topics to be targeted to the elderly	NA
Hickman et al, ³⁴ 2014	Video and web-based interactive education regarding completion of advance directive	NA
Hossler et al, ²⁴ 2010	Interactive, computer-based tool on ACP for patients with ALS	NA
Enguidanos et al, ²⁵ 2011	Brochure on African Americans and hospice care for outpatients with chronic illnesses	NA
Schiff et al, ²⁶ 2009	Booklet on ACP for elderly hospitalized patients	NA
Schubart et al, ²⁷ 2012	Computer-based tool about ACP for elderly outpatients	NA
Volandes et al, ¹⁵ 2008	Two-minute video showing features of advanced dementia and goals of care for elderly Latino outpatients	Volandes et al, ³⁵ 2009; Volandes et al, ³⁶ 2009; and Volandes et al, ³⁷ 2011
Decision Making Tools to Support Current Choices		
Brundage et al, ²⁸ 2000	Booklet with descriptions of treatment options for advanced NSCLC and adverse effects	NA
Cox et al, ⁷ 2012	Ten-page booklet describing chronic critical illness to aid families of patients in the ICU	Study in progress and recruiting, https://clinicaltrials.gov
Dales et al, ²⁹ 1999	Booklet with accompanying audio portion about MV in severe COPD	NA
Deep et al, ¹⁶ 2010	Two-minute video showing features of advanced dementia and goals of care for families of patients with advanced dementia	Volandes et al, ³⁵ 2009; Volandes et al, ³⁶ 2009; and Volandes et al, ³⁷ 2011
Leighl et al, ¹⁷ 2008	Twenty-five-page booklet on lung cancer treatment and outcomes for patients with advanced NSCLC	Leighl et al, ³⁸ 2011
Matlock et al, ³⁰ 2014	Booklet on palliative care, including importance of ACP and clarifying goals and wishes for inpatients undergoing evaluation by a palliative care team	NA
McCannon et al, ¹⁸ 2012	Three-minute video on CPR and mechanical ventilation for families of critically ill patients	Epstein et al, ³⁹ 2013
Mitchell et al, ¹⁹ 2001	Audiobooklet addressing feeding options for families of patients with advanced dementia	Hanson et al, ⁴⁰ 2011
Sepucha et al, ³¹ 2009	Thirty-minute video with booklet that addresses living with metastatic breast cancer	NA
Smith et al, ³² 2011	Printed booklet with review of diagnoses, prognosis, treatment options, and adverse effects for advanced malignant disease	NA
Sudore et al, ²⁰ 2014	Easy-to-read, culturally appropriate, interactive, website that includes a 5-step ACP process and the use of how-to videos that model ACP behavior. The program is focused on teaching elderly patients how to identify what is most important in life, how to communicate that with others, and how make informed medical decisions.	Study in progress and recruiting, https://clinicaltrials.gov
Snyder et al, ²¹ 2013	Printed booklet written at sixth-grade level on advanced dementia and feeding options for families of these patients	Hanson et al, ⁴⁰ 2011
Volandes et al, ²² 2012	Six-minute video depicting the following 3 possible levels of care: full, limited, or comfort focus for patients with advanced cancer	El-Jawahri et al, ⁴¹ 2010; Volandes et al, ⁴² 2012
Wilson et al, ³³ 2005	Booklet with audio portion describing COPD and MV for Canadian outpatients with severe COPD	NA

Abbreviations: ACP, advance care planning; ALS, amyotrophic lateral sclerosis; COPD, chronic obstructive pulmonary disease; CPR, cardiopulmonary resuscitation; ICU, intensive care unit; MV, manual ventilation; NA, not applicable; NSCLC, non-small cell lung cancer; RCT, randomized clinical trial.

poor-quality small RCT⁴⁵ tested a website to promote ACP and palliative care consultation for women with ovarian cancer. This small study found no effect of the website tool on advance directive completion or palliative care consultation.

RCTs of Decision Tools for Current Treatment

Eleven RCTs^{38-42,46-51} tested decision tools to support current treatment choices in serious illness. All but 1 study⁴⁹ improved knowledge (Table 3). Three tools^{40,46,47} also provided evidence of improved clinical communication or choice of treatments.

Seven of these studies^{38,39,41,46-48,51} involved populations with advanced cancer. One high-quality (GRADE A) study of outpatients

with advanced cancer by Clayton et al⁴⁶ found that a booklet prompting communication about prognosis and palliative care led to significantly more patient questions asked during an initial palliative care visit (2.31 times more questions; $P < .001$). Another large high-quality (GRADE A) study by Leighl et al³⁸ examined the impact of a 15-minute online module intended to help patients with metastatic cancer prepare for an initial oncology visit. Although no change in decisional conflict or choice of palliative chemotherapy was observed, the authors noted an increase in satisfaction with ($P = .03$) and ease of decision making ($P < .01$).

In a large high-quality (GRADE A) study by Yun et al,⁵¹ a booklet assisting family members with the decision about disclosure of

Table 2. RCTs of Decision Tools for ACP

Source	Study Population	Intervention and Control	Evidence of Effect on Patient-Centered Outcomes	Rating and Accessibility of the Tool ^a
Pearlman et al, ⁴⁴ 2005	280 Outpatients aged ≥55 y with chronic illness Severity of illness: moderate	Intervention: 52-page workbook <i>Your Life, Your Choices</i> on ACP and 30-min visit with social worker Control: packet of advance directive forms	Moderate impact Increased patient report of ACP discussions after index visit (64% vs 28%; $P < .001$); increased ACP-related notes written by the clinicians (48% vs 23% of the medical records, respectively; $P = .001$)	GRADE B Free online (http://www.rihlp.org)
Sudore et al, ⁴³ 2007	205 Outpatients aged ≥50 y in an urban medical clinic Severity of illness: moderate	Intervention: 12-page advance directive document modified for low health literacy, available in English or Spanish Control: Standard California advance directive	Moderate impact Improved ease of use and understanding (69.1% vs 48.7%; $P < .001$) Increased completion of advance directives in 6 mo (18.5% vs 7.7%; $P = .03$)	GRADE A Free online (http://www.iha4health.org/wp-content/uploads/2014/03/CAHCD_English_no_Script_3.14.13.pdf)
Vogel et al, ⁴⁵ 2013	35 Outpatients with stages III and IV ovarian cancer Severity of illness: moderate to severe	Intervention: website information on ovarian cancer, shared decision making, advance directive completion, and palliative care consultation Control: usual care, clinical documents available on a website	Lesser impact No effect on completion of advance directives ($P = .220$) No effect on palliative care consultation ($P = .440$)	GRADE C Not accessible
Volandes et al, ³⁵ 2009	200 Outpatients aged ≥65 y Severity of illness: moderate	Intervention: verbal description followed by a 2-min video showing features of advanced dementia Control: verbal description of advanced dementia	Lesser impact Increased choice of comfort care as primary goal (86% vs 64%; $P = .003$)	GRADE: A Clinicians may purchase online (http://www.acpdecisions.org/)
Volandes et al, ³⁶ 2009	14 Outpatients aged ≥65 y Severity of illness: moderate	Intervention: verbal description followed by a 2-min video showing features of advanced dementia Control: verbal description of advanced dementia	Lesser impact Increased concordance between patients and surrogates (100% vs 33%; $P = .015$)	GRADE A Clinicians may purchase online (http://www.acpdecisions.org/)
Volandes et al, ³⁷ 2011	76 Rural outpatients aged ≥65 y Severity of illness: moderate	Intervention: verbal description followed by a 2-min video showing features of advanced dementia Control: verbal description of advanced dementia	Lesser impact Increased choice of comfort care as primary goal (91% vs 72%; $P < .001$) Decreased choice of life-prolonging care as primary goal (0 vs 16%; $P = .047$).	GRADE A Clinicians may purchase online (http://www.acpdecisions.org/)

Abbreviations: ACP, advance care planning; GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized clinical trial.

^a GRADE ratings are explained in the Data Synthesis and Analysis subsection of the Methods section.

terminal status to Korean patients with cancer offered no change in the decision to discuss a terminal prognosis, but a significant decrease in decisional conflict ($P = .008$) and caregiver depression ($P = .007$) occurred. Further, both benefits were sustained at 6 months ($P = .03$ and $P = .008$, respectively).⁵¹

An intermediate-quality (GRADE B) study by Peele et al⁴⁷ showed that an online decision tool decreased the choice for adjuvant chemotherapy with limited medical benefits in patients with breast cancer ($P < .05$). In a large study of intermediate quality (GRADE B), Meropol et al⁴⁸ tested an online training module to prepare patients with advanced cancer for their first oncology visit. This intervention improved patients' satisfaction with and ease in decision making.

Two studies^{39,41} examined 2 different video decision making tools for cancer patients. One intermediate-quality (GRADE B) study³⁹ of a 3-minute video on cardiopulmonary resuscitation and mechanical ventilation assessed subsequent decisions by inpatients with late-stage gastrointestinal tract cancer, and they found no change in cardiopulmonary resuscitation or ventilation preferences. However, a high-quality (GRADE A) study⁴¹ testing a similar 6-minute video on the goals of care resulted in a large increase of choice of comfort measures (91% vs 22%; $P < .001$) in a population with malignant glioma. This 6-minute video was also shown to individuals who were newly admitted to nursing homes in another high-quality RCT,⁴² and more patients in the intervention group preferred comfort-oriented care (80% vs 57%; $P = .02$).

Two of the remaining studies^{40,49} addressed patients with advanced dementia. A high-quality (GRADE A) study by Hanson et al⁴⁰ found that a decision making tool on feeding options in patients with advanced dementia in nursing homes led to significant decreases in decisional conflict (Decisional Conflict Scale⁵² score, 1.65 vs 1.97; $P < .001$) and increased the use of a dysphagia diet (89% vs 76%; $P = .04$). An intermediate-quality (GRADE B) Australian study by Stirling et al⁴⁹ of a decision tool on supportive resources for dementia care did not find any change in decisional conflict or treatment preferences.

Finally, Vandemheen et al⁵⁰ led a high-quality (GRADE A) study of a decision tool for patients with cystic fibrosis who were considering lung transplant and found that the tool increased knowledge and realistic expectations while decreasing decisional conflict ($P < .001$). However, the tool did not change the choice to undergo transplant at 12 months.⁵⁰

Discussion

Key Findings

This study is, to our knowledge, the first systematic review of clinical tools to improve communication and decision making for patients facing serious illness. Seventeen RCTs, nearly all of moderate or high quality, form the primary body of evidence for these tools. Study results show that decision tools clearly improve patient

Table 3. RCTs of Decision Tools for Current Treatment

Source	Study Population	Intervention and Control	Evidence of Effect on Patient-Centered Outcomes	Rating and Accessibility of the Tool ^a
Clayton et al, ⁴⁶ 2007	174 Australian outpatients with advanced cancer Severity of illness: moderate to severe	Intervention: 16-page booklet "Asking Questions Can Help: An Aid for People Seeing the Palliative Care Team" with 112 questions on end-of-life care that can be discussed with a physician Control: usual care	Moderate impact Patients in intervention group asked 2.31 times more questions (95% CI, 1.68-3.18; <i>P</i> < .001) of clinicians, discussed more items (17.6 vs 12.7; <i>P</i> = .002), and spent more time per visit (37.8 vs 30.5 min) No change in anxiety or information need at 3 wk	GRADE A Free online (http://www.psych.usyd.edu.au/cempep/docs/comms_Booklet1.pdf)
El-Jawahri et al, ⁴¹ 2010	50 Outpatients with malignant glioma Severity of illness: moderate	Intervention: narrative about choice of 3 levels of medical care followed by a 6-min video depicting elements of life-prolonging, limited care and comfort focus Control: narrative descriptions only	Lesser impact Increased choice for comfort care (91% vs 22%; <i>P</i> < .0001)	GRADE A Clinicians may purchase online (http://www.acpdecisions.org/)
Epstein et al, ³⁹ 2013	56 Ambulatory outpatients with progressive pancreatic or hepatobiliary cancer Severity of illness: severe	Intervention: 3-min video on CPR and MV Control: narrative description of CPR and MV	Lesser impact No change in CPR or ventilator preferences Trend in ACP documentation at 1 mo (40% vs 15%; <i>P</i> = .07) No change in CPR or MV knowledge	GRADE B Clinicians may purchase online (http://www.acpdecisions.org/)
Hanson et al, ⁴⁰ 2011	256 Patients in nursing homes aged ≥ 65 y with advanced dementia Severity of illness: severe	Intervention: audio or printed information on dementia and feeding options Control: usual care	Moderate impact Decreased decisional conflict at 3 mo (DCS score, 1.65 vs 1.97; <i>P</i> < .001) Increased frequency of communication with health care practitioners at 3 mo (46% vs 33%; <i>P</i> = .04) Increase in use of dysphagia diet at 3 mo (89% vs 76%; <i>P</i> = .04)	GRADE A Free online (http://www.med.unc.edu/picare/resources/feedingoptions)
Leighl et al, ³⁸ 2011	207 Outpatients with metastatic colorectal cancer in Canada and Australia Severity of illness: moderate to severe	Intervention: booklet with video that reviews goals of palliative treatment with and without chemotherapy Control: usual care	Lesser impact No change in choice to undergo chemotherapy at 1 to 2 wk No change in decisional conflict or satisfaction Greater increase in knowledge (16% vs 5% increase; <i>P</i> < .001)	GRADE A Not available
Meropol et al, ⁴⁸ 2013	743 Outpatients with known metastatic solid tumors Severity of illness: moderate to severe	Intervention: communication skills training in a 15-min online module that addressed how to prepare for an initial oncology visit and what questions to ask Control: link to the National Cancer Institute website	Lesser impact Increase in overall satisfaction with communication at 3 mo Increase in ease of decision making (<i>P</i> < .01) and with actual decision (<i>P</i> < .001) No change in decisional conflict	GRADE B Not available
Peele et al, ⁴⁷ 2005	432 Outpatients with breast cancer s/p surgery and eligible for adjuvant therapy Severity of illness: moderate	Intervention: online tool estimating prognosis with and without adjuvant therapy Control: general informational pamphlet	Moderate impact Decreased choice of adjuvant therapy (<i>P</i> < .05)	GRADE B Not available
Stirling et al, ⁴⁹ 2012	31 Community-dwelling caregivers of patients with dementia in Australia Severity of illness: moderate	Intervention: workbook with information about community services for the elderly, respite care, and trajectory of decline in dementia Control: usual care	No impact No change in decisional conflict, knowledge, or treatment preferences	GRADE B Not available
Vandemheen et al, ⁵⁰ 2009	151 Outpatients in Canada and United States with CF with FEV ₁ < 40% predicted Severity of illness: severe	Intervention: print and online aid on CF and lung transplant Control: usual care	Lesser impact Improved knowledge (<i>P</i> < .001) and realistic expectations (<i>P</i> < .001) Reduced decisional conflict (DCS score, 11.6 vs 20.4; <i>P</i> = .0007) No change in transplant choice at 12 mo	GRADE A Free online (http://decisionaid.ohri.ca/docs/das/CF_Australia.pdf)
Volandes et al, ⁴² 2012	101 Patients aged ≥ 65 years newly admitted to skilled nursing facilities in Boston area Severity of illness: moderate	Intervention: narrative about 3 levels of medical care (life prolonging, limited care, and comfort focus) followed by a 6-min video depicting these Control: narrative descriptions only	Lesser impact Increased choice for comfort care (80% vs 57% stated they would choose comfort measures; <i>P</i> = .02)	GRADE A Clinicians may purchase online (http://www.acpdecisions.org/)
Yun et al, ⁵¹ 2011	444 Caregivers of terminally ill patients with cancer in Korea Severity of illness: severe	Intervention: video "Patients Want to Know the Truth" with booklet discussing disclosure of terminal status to patients and intrafamily communication Control: National Cancer Institute video and booklet on cancer pain management	Lesser impact No change in decision to discuss terminal prognosis Decrease in decisional conflict initially (<i>P</i> = .008) and at 6 mo (<i>P</i> = .031) Decreased caregiver depression initially (<i>P</i> = .007) and at 6 mo (<i>P</i> = .008)	GRADE A Not available

Abbreviations: ACP, advance care planning; CF, cystic fibrosis; CPR, cardiopulmonary resuscitation; DCS, Decisional Conflict Scale; FEV₁, forced expiratory volume in the first second of expiration; GRADE, Grading of Recommendations Assessment, Development, and Evaluation; MV, manual ventilation; RCT, randomized clinical trial; s/p, status post.

^a GRADE ratings are explained in the Data Synthesis and Analysis subsection of the Methods section.

knowledge and preparation for treatment choices, including ACP, palliative care and goals of care communication, feeding options in dementia, lung transplant in cystic fibrosis, and truth telling in terminal cancer.

Methodological Considerations

Although many trials do not measure outcomes beyond knowledge, 5 published decision tools^{40,43,44,46,47} provide evidence of an effect on clinical outcomes, changes in advance directive documentation, clinical decision making, and treatments received. Three of these tools have been tested in a high-quality RCT, including a tool to promote ACP for persons with low literacy,⁴³ a booklet to prepare patients with advanced cancer to talk with a palliative care team,⁴⁶ and a decision aid for feeding options in dementia.⁴⁰ All 3 tools are currently available for free on the Internet.

The strongest evidence to promote ACP and to prepare patients for future choices supports 2 tools. The first tool is a video ACP tool available to clinicians from the developer that can assist discussions of treatment preferences for the future health state of patients with advanced dementia.^{35,37} The second tool is an advance directive documentation guide available for free on the Internet that is designed for patients with low health literacy.⁴³

Several tools to support immediate clinical choices are available and evidence based. Most of these tools improve knowledge, and some are proven to change actual treatment decisions.^{38,39,41,46-48,51} Only 2 tools are standardized decision aids—one addressing feeding options in dementia care⁴⁰ and one addressing advanced treatment choices in cystic fibrosis.⁵⁰ Decision aids differ in important ways from other decision tools and meet formal standards for framing the presentation of medical information to patients in line with principles of shared decision making.⁶

This study makes a novel contribution to the existing literature by systematically reviewing exportable decision tools designed to empower patients and caregivers in decision making. However, these data have important limitations. Many study populations were small, leaving studies inadequately powered for meaningful results. Study populations all have serious illness, but diagnoses are heterogeneous and limit conclusions about application to specific diseases. More than half of the identified studies used convenience samples and followed a pre-intervention-postintervention study design. The nature of interventions designed to improve these outcomes often results in a non-blinded study design. We only searched for articles published since 1995, so we might have missed earlier articles. However, our review did not reveal any articles before 1998; therefore, this possibility seems less likely. Finally, this review is limited to published research. The analysis might have had a publication bias toward positive studies that could skew our review. However, some of the studies reviewed reported negative findings, so this possibility seems less likely.

Implications

Given the clear need to improve shared decision making in serious illness, improving this body of evidence should be a research priority. Research is needed to test decision aids for major serious illnesses, such as advanced heart failure or end-stage renal disease. Because the effect on knowledge is well established, future research needs to focus on outcomes measuring the effect of the change in knowledge on treatment decisions, receipt of care consistent with preferences, and satisfaction with care. Furthermore, decision aids for the seriously ill could reduce health care intensity and costs by decreasing unwanted major high-cost interventions or hospitalizations; these outcomes have not been studied.

Tools to promote patient engagement in treatment decisions are a policy priority in the United States since the passage of the Affordable Care Act.⁵³ Therefore, investigators with proven tools may consider the importance of implementation research and effective dissemination strategies to ensure that clinicians and patients can truly benefit. Making proven decision tools available online or embedding them in electronic health record systems would be appropriate first steps. However, meaningful adoption of this novel practice may require peer leadership, incentives, new time and space in clinical settings, training, and feedback.

This body of evidence is promising, yet it lags far behind the rapid dissemination of tools—primarily for ACP—that are developed outside a clinical research framework. A recent review by the Agency for Healthcare Research and Quality⁵⁴ combed scientific and gray literature sources to describe a multitude of published ACP tools that are diverse in quality and rarely supported by evidence of effectiveness or patient benefit. Unlike our study, that review excluded decision aids for current health care choices, which may be most relevant once serious illness develops. Healthcare organizations may be more successful at improving shared decision making if they demand decision tools with evidence of effectiveness. This phenomenon suggests a significant opportunity for collaboration in implementation, blending the best of decision science with the broad public reach of innovations in web-based technology.

Conclusions

A small but promising body of research demonstrates the clinical potential to improve patient engagement with tools to enhance decision making in serious illness. A small number of these tools are supported by evidence of their impact and are available for clinical practice. Future research should expand the work to new decisions in serious illness and emphasize outcomes beyond knowledge, such as care consistent with preferences and satisfaction with care.

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Invited Commentary

Decision Aids in Serious Illness Moving What Works Into Practice

James A. Tulsky, MD

Shared decision making is often challenging and never entirely rational.¹ Even seemingly simple decisions, such as taking antibiotics for an upper respiratory tract infection or re-

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pairing a fractured bone, may encompass trade-offs, are influenced by cognitive biases, and can be clouded by emotion. Serious illness amplifies these biases and their effects. Decision making is even more complicated in the setting of advance care planning, when patients are trying to decide for their future selves rather than their current selves.

When seriously ill patients make decisions that are uninformed, not reflective of deeply held values, or clouded by unaddressed emotional considerations, profound negative consequences may follow. In some cases, patients may receive treatments and outcomes inconsistent with their goals. In others, decisional conflict can lead to a patient's emotional distress or, for caregivers, traumatic bereavement.² In situations where patients, families, and physicians default to undesired and aggressive nonbeneficial care, not only are patients harmed but resources are wasted. In response to these known risks, a robust literature, echoed in the recent Institute of Medicine publication *Dying in America*, emphasizes the need to enhance advance care planning and improve decision making for patients with serious illness.³ However, understanding complicated medical information, confronting the emotions presented by considering death and other poor outcomes, and needing to manage uncertainty challenge patients' and phy-

sicians' abilities to achieve true shared decision making in the setting of serious illness.

Decision aids have been developed to help patients navigate a wide range of diagnostic and treatment choices.⁴ By giving patients information in plain language that they can readily understand and by making clear the trade-offs that they face, decision aids aim to ease the choices that patients make and increase the likelihood that these choices reflect their preferences most accurately. Decision aids promote shared decision making, creating informed patients who can ensure that their values, needs, and wishes are taken into account. The review by Austin et al⁵ seeks to identify decision aids that have been tried in a population of seriously ill patients and to systematically evaluate their success.

This exhaustive and rigorous study characterizes all the work in this area and, despite limitations of the data, identifies consistent findings and a clear story. Even though advance care planning is widely recommended and countless patients with serious illness face major treatment decisions every day, few rigorously designed studies have attempted to introduce decision aids into this setting. The authors uncovered 17 randomized clinical trials: 6 for advance care planning and 11 for current treatment decisions. These trials have found that decision aids in this population are acceptable and feasible and can modify patients' expressed preferences. In advance care planning, they can increase the number of discussions with physicians and the number of advance directive documents completed by patients. When used to assist with a current treatment decision, they may increase ease of decision making, reduce decisional conflict, and modify the decisions made. One