D. Key Questions 2 and 3:

2. What patient, family, and healthcare system factors are associated with better or worse outcomes at end of life?

3. What processes and interventions are associated with improved or worsened outcomes?

Elements associated with family experience, especially caregiving

Caregiver burden includes the full spectrum of potential concerns that families and other informal caregivers face in caring for someone with advanced illness. These concerns include but are not limited to mental and physical health, financial well-being including out-of-pocket costs and job loss, and interpersonal stresses. We did not generally assess bereavement, which we defined as after-death emotional concerns, but we otherwise considered the full impact of illness on caregiver well-being. If studies included bereavement as an outcome but also addressed other topics that were central to the review, they were included. However, studies on bereavement alone were excluded.

We evaluated six systematic reviews that potentially dealt with the subject of caregiver burden, addressed the project questions, and met implicit quality criteria. Three dealt with outcomes of caregivers for patients with dementia or other chronic illness; three others dealt with cancer patients or life-threatening illnesses. We went beyond the systematic reviews by including other interventions to reduce caregiver burdens at the end of life published after these systematic reviews or published at any time if not already addressed in a systematic review. In total, we reviewed an additional thirteen intervention studies. Finally, we explored the observational literature that addressed selected topics. Specifically, we identified prospective, observational cohort studies addressing any of our selected symptom topics and that also presented data separately by race, selected disease cohorts, or selected sites of care. Seventeen observational studies that met these criteria are discussed here.

The remainder of this section summarizes the systematic reviews, meta-analyses, intervention, and observational studies relevant to patient and caregiver burden. Summaries of the association of patient, family, and health system factors to caregiver burden and the effectiveness of interventions in improving caregiver burden are found at the conclusion of Chapter 3.
Table 5. Systematic Review—Caregivers

<table>
<thead>
<tr>
<th>Systematic Review</th>
<th>Caregiver Outcomes</th>
<th>Date Search Concluded</th>
<th>Date Published</th>
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</thead>
<tbody>
<tr>
<td>Acton &amp; Kang 255</td>
<td>Caregiver burden (dementia patients)</td>
<td>1999</td>
<td>2001</td>
</tr>
<tr>
<td>Acton &amp; Winter 256</td>
<td>Burden, stress, anxiety, coping, life satisfaction, morale, perceived physical health, and rate of institutionalization (dementia, advanced chronic illness patients)</td>
<td>2001</td>
<td>2002</td>
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<tr>
<td>Yin, Zhou, &amp; Bashford 257</td>
<td>Caregiver burden (dementia and frail patients)</td>
<td>2000</td>
<td>2002</td>
</tr>
<tr>
<td>Higginson, Finley, et al. 14</td>
<td>Pain, other symptoms, quality of life, satisfaction, referral to other services, caregiver satisfaction, caregiver burden/morbidity, home death rates, health service use, costs (progressive, life-threatening illness patients)</td>
<td>1999</td>
<td>2002</td>
</tr>
<tr>
<td>Higginson &amp; Gysels 72</td>
<td>Caregiver burden, quality of life, satisfaction, anxiety, problem solving/coping skills, pain management, activity goals, knowledge, psychosocial status, stress management (cancer patients)</td>
<td>2001</td>
<td>2001</td>
</tr>
<tr>
<td>Wilson 258-260</td>
<td>Patient and family satisfaction with care, well-being and quality of life, family needs, and EOL outcomes, including effects of case management on those outcomes</td>
<td>2003</td>
<td>Unpublished</td>
</tr>
</tbody>
</table>

Systematic Reviews and Caregiver Burden

We identified eight systematic reviews and meta-analyses that were relevant to family or informal caregiving and met implicit quality criteria (see Table 5). Three dealt with outcomes of caregivers for patients with dementia or other chronic illness; five others dealt with cancer patients or other life-threatening illnesses.

Acton & Kang (2001)255 reviewed 46 studies (experimental, quasi-experimental, and one group pre-post designs) published between 1982 and 1999. Family caregivers of dementia patients were studied; no further details were given on the patients receiving the care. The caregivers were not caring for “terminally ill” patients or patients at the end of life. Twenty-four studies testing 27 interventions were included in the quantitative analysis (three studies tested two different interventions). Interventions included psycho-education (n=10), education (n=5), respite care (n=4), counseling (n=4), multi-component interventions (n=3), and support group (n=1). A total of 1,254 participants (range: 11 to 180, with a mean of 51 participants per study) were included in the meta-analysis (866=T; 388=C). The outcome assessed was caregiver burden. The analysis reported that the interventions had no effect on caregiver burden, and in some cases the effect of the intervention was negative or the control group scores improved more than those of the treatment group. Only one multi-component intervention and one respite intervention significantly reduced caregiver burden. Pooled analyses of treatments that evaluated subjective and objective burden separately showed that interventions had no significant beneficial effect on either type of burden.

Acton and Winter,256 in a review that partially overlapped the review conducted by Acton and Kang,255 examined 73 published and unpublished research reports (1991 to 2001) and included controlled trials and pre-post designs. All types of caregivers of patients with dementia and other diseases were included. The studies appeared to span patients with all degrees of
severity; no “end of life” studies are specifically mentioned. Less than 50% of care receivers had dementia. A wide range of caregiver interventions designed to lessen the negative impact of caregiving or improve the positive aspects of caregiving for caregivers to patients with dementia or other diseases were included. Outcomes included burden, stress, anxiety, coping, life satisfaction, morale, perceived physical health, and rate of institutionalization. Studies were grouped by intervention type (education, support and education, counseling, respite, case management, and multi-component) and evaluated for strengths and weaknesses in design, sample, intervention, and outcomes. Overall, 32% of the study outcomes were changed in the desired direction after intervention.

Education interventions (23 studies, sample range: 2–95) focused on individualized, home-based programs delivered by nurses one-on-one over time periods ranging from one to eight months (resulting in higher intervention intensity than other education intervention strategies). About one-third of 90 outcome variables measured were reported to be statistically significant in the desired direction (depression, tension, anger, burden, negative affect). Knowledge, coping, and life satisfaction were significantly increased in three studies. Caregiver support and education intervention studies (14 studies, sample range: 26–53) were primarily delivered as individualized education to a caregiver. Only three studies were conducted in a group, community-based format and a fourth was a computerized intervention. Three of the 18 nursing outcomes were significantly changed in the desired direction (burden, stress, and decision confidence) and one study found stress and burden to be significantly increased. Counseling interventions, designed to help caregivers understand the behavioral symptoms exhibited by the demented care receiver and their own reactions to the behavioral symptoms, were tested in four studies (sample range: 5–39). One study reported significant changes in outcomes (increased knowledge and morale) after group counseling. Respite care, including eight studies evaluating day care and eight studies evaluating inpatient or in-home respite (sample range: 7–264) reported that the combination of use and duration varied considerably across studies, making it difficult to determine intervention effect. Intensity of interventions ranged from one to five days per week and duration ranged from one to four months. Case management (assessment, planning, coordination, collaboration, and monitoring by a professional case manager) was evaluated in six studies (sample range: 12–4,151). One study reported a significant reduction in stress. Twelve multi-component interventions (sample range: 5–86) were reviewed. Both positive and negative consequences of caregiving were measured as outcomes; most studies reported mixed results. Two studies found the rate of institutionalization significantly reduced. The results of the meta-analysis provide little support for the interventions studied.

Yin, Zhou, and Bashford (2002) examined 26 studies that had comparison groups (single-group pre-post test designs were excluded), published between 1985 and 2000. All types of caregivers were included. The mean age of the caregivers was 60 years; 79% were women and 86% were White. An average of 80% of the caregivers lived in the same household as the care receivers. About half of the care receivers had dementia (the rest had other types of chronic illnesses). The care receiver’s mean age was 79 years old. There was no explicit identification of “terminally ill” patients or patients “at the end of life.”

The 26 studies included 18 addressing group caregiver interventions and 8 addressing individual caregiver interventions. The total sample size was 1,970 for the combined interventions and 472 for the individual interventions. Caregiver burden was the primary outcome in the group intervention studies (although only 10/18 used the same instrument—the
Zarit Burden Inventory). No details on the individual intervention outcomes were provided. Studies were evaluated on effect size, study design, type of intervention, duration and frequency of intervention, method of assignment, type of instrumentation, time of posttests, and study site, characteristics of the study samples, and characteristics of researchers.

The weighted mean effect size for all studies was .41 (95% CI, 0.32–0.51), indicating a moderate beneficial treatment effect of group interventions on caregiver burden. Subgroup analysis indicated the mean effect size was larger for individual intervention studies (0.48) than for group intervention studies (0.26). The mean effect size of the quasi-experimental studies (0.89) was more than three times that of the true-experimental studies (0.26) but generally consistent with other research.

Higginson, Finlay, Goodwin, Cook, Edwards, Hood, Douglas, and Normand conducted an assessment of five systematic reviews (1977–1999, 43 studies) of palliative care team interventions on patients’ pain, other symptoms, quality of life, satisfaction, referral to other services, and therapeutic interventions and on caregiver pre-post bereavement burden/morbidity and satisfaction with care. Disease severity, amount of family support, training and experience of team members in palliative care, whether the team had an occupational or physiotherapist, and team links to social services were not described in many of the caregiver-relevant studies and were thus excluded from the analysis. However, the general conclusions of each paper assessed were similar. Overall, the analysis indicated small beneficial effect of palliative care services on patient and caregiver outcomes, with the strongest support for home care services. Similar or improved outcomes were found for patient satisfaction, patient pain and symptom control, and family anxiety for hospice and palliative care services when compared to conventional care. There was a lack of good-quality evidence on which to base conclusions, and there was no evidence of an effect on other quality of life measures.

Gysels and Higginson conducted a systematic review of the effectiveness of different interventions targeted at healthcare professionals, the structure of healthcare delivery, or the care delivered to improve supportive and palliative care to cancer patients. In this review, 22 interventions targeted at improving care for families and informal caregivers (including bereavement) were identified. Interventions included home nursing care (four studies), respite services (three studies), social networks and activity enhancements (two studies), problem solving and education (three studies), and groupwork (ten studies). Nine of the interventions were targeted to caregivers only. Limitations of the data included a lack of outcome evaluation designs, small sample sizes and a reliance on intervention descriptions and formative evaluations. Only two quasi-experimental evaluations were included. Interventions, patient and caregiver characteristics, and outcome measures were not well described in the review. The evidence in this analysis appears to contribute more to understanding the feasibility and acceptability of these interventions than to their effectiveness.

Caregivers reported high satisfaction with home care services and described them as useful. However, the high levels of psychological morbidity and unmet need reported in these samples of caregivers using home nursing care in both cancer and palliative care indicated that such generic supportive nursing care does not meet all caregiver needs. Caregivers using inpatient and home hospice care reported a greater reduction in anxiety and higher satisfaction compared to conventional care in one RCT. Another study of home hospice found caregiver quality of life remained stable over four weeks. An RCT of a hospital at home for terminally ill patients in the last two weeks of life reported no significant difference between the intervention and standard
care and low uptake of the intervention due to caregiver inability to cope. A formative qualitative evaluation of a community palliative care service (home care, day care, and respite as a single service) reported that caregivers valued the single point of contact, that it felt like a “home away from home,” and that it helped them overcome reluctance to access other services. A longitudinal RCT of home care nursing on caregiver psychosocial status of caregivers with and without physical problems of their own reported an improvement in psychosocial status for those caregivers with physical problems and at risk for psychological morbidity. A psycho-education program for cancer caregivers reported that perception of burden did not worsen even when caregiving tasks increased in intensity. Widely varying respite care services reported high satisfaction in caregivers.

Descriptive data were reported on respite care. One study, using a single group retrospective questionnaire (n=190), reported over 90% satisfaction among caregivers (though 33% felt the service had been offered too late). Social networks and “activation” programs for relatives of cancer patients aimed to promote increased social activity. One controlled trial was reviewed, with an age- and sex-matched comparison group (50 intervention and 45 comparison caregivers) and reported the intervention caregivers had significantly higher social activities during care receiver cancer treatments and significantly more involvement in personal activities preceding the death of the patient. One RCT of a one-to-one intervention designed to provide support, education, and build problem-solving and coping skills (n=38) reported the intervention effective only for a distressed sub-sample of cancer caregivers. This burdened sub-sample of caregivers was better at dealing with pressing problems following the intervention (n=11) compared to controls (n=18). Another one-to-one intervention on cancer pain education (n=50) reported significant improvements on knowledge/attitudes to pain, pain management, and caregiver burden. A multidisciplinary group support designed to alleviate caregiver stress from lack of knowledge is described, but no data are reported.

An RCT of group work interventions for patients and caregivers (n=25), designed to provide support and information to caregivers, reported that spouses who attended the intervention had significantly higher knowledge scores, achieved activity goals, coped better, and were more satisfied with care. However, psychosocial adjustment did not differ between the two groups. An observational study of group work on quality of life reported no differences in quality of life or coping strategies. A descriptive evaluation of a combined patients’ (n=73) and caregivers’ (n=54) group support for cancer care reported that the provision of information and education promoted understanding and facilitated coping, and the familiarity with the facts and feelings involved reinforced participants’ confidence. A retrospective single group evaluation of a monthly support group for cancer patients and families reported that 26% of the respondents felt more anxious/worried and 29% felt sadder. Another observational study of group support on quality of life in cancer patients and their family (n=12) compared to a control (n=12) and an ongoing support group (n=8) found no significant differences in quality of life or coping strategies.

The review supports the small body of evidence on the effectiveness of interventions for caregivers to cancer patients. Despite caregivers’ recognition of unmet need, they report some improved outcomes. However, one study indicated that these interventions could be detrimental to caregivers. Based on the analysis, the authors concluded that no single service model appears either acceptable or effective for the broad range of caregivers. Home care appears to produce high satisfaction. The authors concluded there is little evidence supporting the effectiveness of
respite services, support groups, and one-to-one individual interventions. Groupwork interventions reported the most effect but they had low uptake and are acceptable primarily to caregivers with specific profiles. The evidence suggests there is a high rate of unmet need in caregivers using palliative care services that highlights the limited scope of some of these interventions.

Wilson’s systematic review (in press) identified 11 studies and three systematic reviews of care/case management on end-of-life care. Of five research articles examining case management interventions on patient quality of life, two reported an increase in patient quality of life while three other studies reported no significant impact. However, the role of case management in the interventions varied significantly; in many cases, the case management function was not as care coordinator or problem solver. Three studies assessing the impact of case management on caregiver burden reported a beneficial impact on family caregivers. In general, case management was reported to be a means of reducing family caregiver burden, although only three studies were evaluated. In addition, the quality of the studies reviewed was poor, few RCTs were identified, and the exact interventions were inadequately described.

Additional Interventional Studies and Caregiver Burden

We identified 13 additional studies assessing interventions and caregiver burden.

One RCT (n=203) reported no effect for nurse coordination for cancer patients in the community. Specifically, there were no significant differences in time between last follow-up and death, in symptom experience, or in use of pharmacologic treatments. A few significant differences arose in caregiver reports of type, severity, and effectiveness of treatment of patients’ symptoms in last week of life. The groups did not differ on the hospital anxiety and depression scale, social support, and quality of life, ADL assistance needs, unmet needs, financial impact, use of social services, and satisfaction w/ care.

A multi-site RCT compared enhanced home-based primary care (HBPC) in 16 VA hospitals compared to usual HBPC care. Enhanced care consisted of HBPC services plus systematic screening to identify high-risk patients, an emphasis on continuity of care, 24-hour telephone access, and the management of patients across organizational boundaries involving care management by HBPC physician serving as the primary care provider. Terminal patients in the intervention group significantly improved on eight health-related quality of life scales (emotional, social, bodily pain, mental health, vitality, general health), with the greatest improvement in emotional function. No difference was found in terminal patient satisfaction over the study period. Caregivers to terminal patients also reported significant health-related quality of life improvements (p<.05 overall) in all but two dimensions (vitality, general health), with greatest improvement in emotional function (13-point gain vs. usual care). Caregivers also reported significant gains in satisfaction with patient care (p<.001), except for one personal satisfaction item. An 8% reduction in hospitalizations and mean number of hospitalizations in enhanced HBPC program was reported in the first six months, but this was not sustained at 12 months. A 22% reduction in utilization was reported in those with the most disability. Patient and caregiver benefits were accompanied by a 6.8% increase in total costs of care at six months and 12.1% increase at 12 months. The Jadad score for this study was 3.

One RCT evaluated an intervention designed to improve end-of-life decision-making and reduce the frequency of a mechanically supported, painful, and prolonged process of dying,
conducted in two phases. Phase I was a two-year prospective observational study with 4,301 patients, and phase II was a two-year RCT with 4,804 patients and their physicians (randomized by specialty group) to usual care or an intervention consisting of prognosis estimates to physicians, specially training nurses to improve communication and decision-making among seriously ill hospitalized patients, families, and healthcare teams. Phase I documented shortcomings in communication, frequency of aggressive treatment, and the characteristics of hospital death. Only 47% of physicians knew when their patients preferred to avoid cardiopulmonary resuscitation (CPR); 46% of DNR orders were written within two days of death; 38% of patients who died spent at least ten days in an intensive care unit (ICU); and, for 50% of conscious patients who died in the hospital, family members reported moderate to severe pain at least half the time. In the RCT, patients experienced no improvement in patient-physician communication (e.g., 37% of control and 40% of intervention patients discussed CPR preferences) or in five targeted outcomes, i.e., incidence of timing of written DNR orders (adjusted ratio, 1.02, 95% CI, 0.90 –1.15), physicians’ knowledge of their patients’ preferences not to be resuscitated (AR, 1.22; 95% CI, 0.99–1.49), number of days spent in an ICU, receiving mechanical ventilation, or comatose before death (AR, 0.97; 95% CI, 0.87–1.07), or level of reported pain (AR, 1.15; 95% CI, 1.00 to 1.33). The intervention also did not reduce use of hospital resources (AR, 1.05; 95% CI, 0.87–1.07). The Jadad score for this study was 3.

An evaluation of a hospital-at-home intervention \(^{83}\) (n=198, 86% of 229 referred patients and 144 caregivers, 73% of 198 referred caregivers) on patient’s quality of care, likelihood of remaining at home in their final two weeks of life, and general practitioner (GP) visits. The study reported no conclusive evidence that the hospital-at-home service for terminally ill patients increased the likelihood of remaining at home during the final two weeks of life. However, the service was associated with fewer GP out-of-hours visits. All respondent groups (GP, nurses, caregivers) rated the intervention favorably when compared to standard care but emphasized different aspects. Nurses rated services as better than standard care in terms of adequacy of night care and support for the caregiver; GPs positively rated the service in terms of the reduction of anxiety and depression in patients; and caregivers rated the service positively in terms of control of patient symptoms (pain and nausea). Overall, the authors concluded the service provided better quality of care. The Jadad score for this study was 3.

A cluster randomized trial of palliative care services for unspecified terminally ill patients and their caregivers \(^{84}\) (discussed in satisfaction) measured the place of death and satisfaction with care. This same trial reported impacts of the palliative care intervention on caregiver quality of life \(^{262}\) using a larger sample (517 caregivers) and reported similar results. Five of eight subscales of health-related quality of life scores declined between baseline and final follow-up (one to two months after patient’s death). As expected, HRQOL returned to baseline by the end of the study. The intervention ameliorated declines in role limitation due to emotional problems and mental health, but scores for the other three subscales showed smaller and almost linear decline. There were extremely low response rates in both groups, which undermines the findings in this study. The Jadad score for this study was 3.

The Resources for Enhancing Alzheimer’s Caregiver Health (REACH) project \(^{263-268}\) a six-year multi-site research program funded by the National Institute on Aging (NIA) and the National Institute of Nursing Research (NINR), focused on testing the most promising home and community-based interventions for maintaining and improving the health and quality of life of caregivers if dementia patients. Fifteen well-defined interventions (nine active and six control
group conditions) were implemented (Birmingham, Boston, Memphis, Miami, Palo Alto, and Philadelphia) and assessed common outcome measures. The interventions consisted of psychosocial and psycho-educational services, behavioral interventions, environmental modifications, and technology interventions. Three of the sites included a minimal support telephone contact control group and three sites included usual care control conditions. The study population (n=1,222) included African American, Cuban American, Mexican-American, and White American family caregivers of patients with Alzheimer’s disease (AD) and related disorders (ADRD). A common set of measures was collected at all sites at baseline, 6 months, 12 months, and 18 months following random assignment to an intervention condition. Outcome measures included caregiver mental health or well-being and depression; social support; caregiver burden; religiosity; service utilization; caregiver and care recipient physical health and medication usage; and care recipient behavior and cognition.

The pooled effects of 15 site specific REACH interventions (nine active and six control group conditions) on caregiver burden and depressive symptoms following six months intervention and initial analysis of overall treatment effects by categories of caregiver race/ethnic identity, gender, educational level, and relationship to care recipient using an intent-to-treat model were reported. Three sites (Birmingham, Boston, Philadelphia) tested a single active intervention (skills-training, telephone-linked computer [TLC], environmental skill building program [ESP]). Three sites implemented two active interventions: Memphis (behavior and enhanced care), Miami (family-based structural multi-system in home intervention [FSMII] and FSMII combined with computer telephone integration system [CTIS]), and Palo Alto (coping with caregiving class and enhanced support group). Two sites used modified usual care control groups (Boston and Philadelphia) in which caregivers received information packets only. One site (Memphis) provided information and referral and three other sites (Birmingham, Miami, and Palo Alto) utilized a minimal support control (MSC; information and empathetic listening).

Using meta-analysis, the pooled treatment effect for burden was statistically significant (p=.022), although the difference was small. Overall, caregivers in the active interventions across the REACH sites showed lower values in burden associated with patient behavior problems than controls. No intervention showed a statistically significant effect for caregiver burden, although all scores did improve for active interventions. In contrast to burden, the pooled treatment effect for CES-D was not statistically significant (p=.095). Only one site (Miami) reported a significant reduction in depressive symptoms (p=.034) in the combined family therapy plus technology treatment condition compared to controls. The family-therapy intervention did not have a significant effect on depressive symptoms by itself. Overall, the REACH interventions produced only a modest treatment effect, but this is consistent with results of other recent meta-analyses. The magnitude of the effect sizes for the combined active REACH interventions on caregiver burden (0.15 standard deviation units) and Miami’s FSMII + CTIS intervention on depressive symptoms (0.23 standard deviation units) fall within the range of effect sizes reported by others (Sorenson, et al., 2002). The magnitude of change on burden for the REACH combined active intervention groups compared to control conditions was 10% (score range=0–96). This change is equivalent to the decrease or elimination of two very bothersome behaviors, such as repetitive vocalization or waking at night. The relatively small overall effects of REACH may be a result of the complex pattern of significant outcomes observed for various subgroups. Across sites, women and those with high school or less education who were in active interventions reported reduced burden compared to controls. In contrast, men and those with higher education levels did not show significant benefit from the interventions. Caregivers in active interventions who were
Hispanic, those who were non-spouses, and those who had less education reported lower six-month depression scores than controls. These findings suggest that the combined interventions had an effect for those caregivers in most need of support.

The Miami REACH project investigated the efficacy of Structural Ecosystem Therapy (SET), based on the Brief Family Therapy intervention for treating behavior problems in dementia patients and SET+CTIS, a system designed to augment SET by facilitating linkages of the caregivers with their family and with supportive resources outside the home. The sample included 225 family caregivers (114 Cuban-American and 111 White American) of patients with Alzheimer’s disease and related dementias (ADRD). Overall, there were significant differences by caregiver type, intervention, and ethnicity on depressive symptoms. Caregivers in the combined family therapy and technology intervention (SET+CTIS) experienced a significant reduction (five or more points for Cuban-American and White non-Hispanic daughters and Cuban-American husbands) in depressive symptoms at 6 months and at 18 months compared to all other intervention groups. Husband caregivers had lower CES-D scores than wife or daughter caregivers in all intervention groups, and Cuban-American caregivers (husbands and daughters) experienced the most benefit from the interventions, particularly the SET+CTIS.

The Memphis REACH project compared two structured, parallel interventions, Behavior Care (BC) and Enhanced Care (EC) in a 24-month clinical trial. Behavior Care interventions focused only on improving the caregiver’s management of the care recipient’s behavioral problems using 25 pamphlets addressing particular behaviors. Enhanced Care interventions focused on these same behavior problems but also on improving the caregiver’s own well-being in response to the behavior problems through 12 additional pamphlets geared to caregiver well-being. Both models were delivered by a master’s prepared health educator in an office setting. One-hundred sixty seven caregiver-patient dyads were randomized into BC (n=85) and EC (n=82). At two months, 7 of the original 17 active caregiver-patient dyads remained for analysis. Difference in completers vs. noncompleters was based on length of caregiving (shorter length of caregiving more likely to complete). Of final caregiver-patient dyads (n=167), 66 were Black American, 99 were White-Caucasian, and 2 were other race. Caregivers were predominantly women and tended to be spouses or daughters. Results showed that caregivers receiving only BC had significantly worse outcomes for general well-being and a trend toward depression compared to caregivers receiving EC. There was an overall improvement in both groups for bother associated with care recipient behaviors. No racial/ethnic differences were reported.

The Birmingham REACH project implemented a multi-component interventions intended to address the common needs of White and African-American family caregivers while remaining responsive to cultural issues. One hundred forty caregiver-patient dyads (White=70 and African American=70) were randomly assigned to either a skills training condition (ST) or a minimal support (MS) control condition. One hundred eighteen dyads completed the six-month assessment (White=70; African American=48). Significant differences between White and African American caregivers included: White caregivers more likely to be spouses and African American caregivers more likely to be non-spouses. White caregivers were significantly older and reported higher household occupational status than African American caregivers. African American care receivers had lower educational attainment and demonstrated greater cognitive impairment than White care receivers. Results demonstrated that both interventions were well received by caregivers. Caregivers in both groups and both races reported decreasing levels of problem behaviors and appraisals of behavioral bother, and increased satisfaction with leisure
activities over time. On one measure of appraisal of distress related to behavior problems, White caregivers showed more improvement in the minimal support control condition, and African American caregivers showed the greatest improvements in the skills training condition. No significant effects were found for race, treatment group, their interaction, or time for depression or anxiety. A significant treatment by race by relationship interaction was found with the largest decreases in the number of problem behaviors found for White spouse in the MS condition and for African American spouses in the ST condition.

The Philadelphia REACH project\textsuperscript{267} examined the six-month effects of an Environmental Skill-Building program (ESB), as well as race, relationship, and gender on caregiver well-being and care recipient functioning. One hundred and ninety family caregivers of community-residing dementia patients completed the six-month follow-up. Caregivers were randomized to a usual care control group (UC) or intervention group (IG) that received five home contacts and one telephone contact by occupational therapists, who provided education, problem-solving training, and adaptive equipment. Baseline and six-month follow-up included self-report measures of caregiver objective and subjective burden, caregiver well-being, and care recipient problem behaviors and physical function. Compared with controls (n=101), intervention caregivers (n=89) reported less upset with memory-related behaviors, less need for assistance from others, and better affect. Intervention spouses reported less upset with disruptive behaviors; men reported spending less time in daily oversight; and women reported less need for help from others, better affect, and enhanced management ability, overall well-being, and mastery relative to controls. Statistically significant treatment differences were not found for hours helping with ADLs and IADLs, perceived change in somatic symptoms, White versus non-white caregivers, or care recipient outcomes.

The Boston REACH project\textsuperscript{268} examined the 12-month effects of a computer-mediated automated interactive voice response (IVR) intervention designed to assist family caregivers managing persons with disruptive behaviors related to Alzheimer’s disease (AD). One hundred caregivers were randomized into treatment (n=49) and control conditions (n=51). The intervention provided caregiver stress monitoring and counseling information, personal voice-mail linkage to AD experts, a voice-mail telephone support group, and a distraction call for care recipients. Measures of the caregiver’s appraisal of the bothersome nature of caregiving, anxiety, depression, and mastery were repeated at baseline, 6, 12, and 18 months. Results showed a significant intervention effects for participants with lower mastery at baseline on all three outcomes: bother (p=.04), anxiety (p=.01), and depression (p=.007). Wives exhibited a significant intervention effect in the reduction of bothersome nature of caregiving (p=.02). Wives and those with low mastery and high anxiety benefited most from the automated telecare intervention.

**Observational Studies and Caregiver Burden**

A number of prospective cohort and observational studies examined the impacts of caregiving on family caregivers. Two of these were discussed previously (see Satisfaction).\textsuperscript{27, 99} Seven studies evaluated the overall impacts of caregiving upon terminally ill patients. Covinsky, Goldman, Cook et al.,\textsuperscript{270} in a prospective cohort study (n=2,129) of outcomes, preferences, and decision-making in seriously ill hospitalized patients found that one-third (34\%) of patients required considerable caregiving assistance from a family member. In 20\% of cases, a family member had to quit work or make another major life change to provide care for the patient. Even though almost all patients had health insurance, loss of most or all of the family savings was
reported by 31% of families, whereas 29% reported the loss of the major source of income. Patient factors independently associated with loss of the family’s savings included poor functional status (OR 1.40; 95% CI 1.10–1.78), lower family income (OR 1.74; 95% CI 1.37–2.21 for those with annual incomes below $25,000 and young age (OR, 2.85; 95% CI 2.13–3.82 for those younger than 45 years of age compared to those 65 or older). Families of younger, poorer, and more functionally dependent patients are the most likely to report loss of most or all of the family’s savings to a serious or fatal illness.

Emanuel, Fairclough et al. conducted a survey of 988 terminally patients and their caregivers in six randomly selected areas of the United States to determine how their needs for assistance were met and the frequency with which they received such assistance from family members and paid or volunteer caregivers. Of the 988 terminally ill patients, 59% were over the age of 65 years and 51.5% were women. The most frequent terminal illness was cancer (52%), followed by heart disease (18%), and chronic obstructive pulmonary disease (11%). Four percent of the sample were in an institution (nursing home, hospital, or residential hospice), the rest were living in the community. Seventy-two percent of caregivers were women and 96% of caregivers were family members. A need for assistance was reported by 87% of the patients, including help with transportation (reported by 62%), homemaking services (55%), nursing care (29%), and personal care (26%). Most patients relied completely on family members and friends for assistance. Only 15.5% of patients relied totally on paid assistance for more than half of the care they needed. Volunteers (unpaid helpers who were not family members) provided less than 3% of all care. In addition to medical care, dying patients often need many types of assistance. Family members, primarily women, provided the majority of assistance with non-medical care.

In a subsequent analysis of this data, Emanuel, Fairclough et al. found that 35% of the sample had substantial care needs and that those with substantial care needs were more likely to report that they had a subjective sense of economic burden (44.9% vs. 35.3%; difference 9.6 percentage points [95% CI, 3.1–16.1]; p=0.005). In addition, 10% of these families household income was spent on health care (28% vs. 17%; difference, 11 percentage points [CI 4.8–17.1]; p<0.001) and they or their families had to take out a loan or mortgage, spend their savings, or obtain an additional job (16.3% vs. 10.2%; difference, 6.1 percentage points [CI 1.4–10.6]; p=0.004). Patients with substantial care needs were more likely to consider euthanasia or physician-assisted suicide (p=0.001). Caregivers of these patients were more likely to have depressive symptoms (p=0.01) and to report that caring for the patients interfered with their lives (p=0.001). Caregivers of patients whose physicians listened to patients’ and caregivers’ needs had fewer burdens. This study demonstrated that substantial care needs are an important cause of the economic and other burdens imposed by terminal illness.

Brazil, Bedard, Willison, and Hode examined the effects of palliative caregiving in the home for 151 family caregivers to terminally ill cancer patients. The majority of respondents were the female spouses (79%) of the patient. The numbers of caregivers providing assistance in specific functional activities were bathing (88%); mobility 81%; dressing and undressing (76%); toileting (67%); and assistance at night (64%). Forty-one percent of caregivers reported that they had been providing some form of care for over one year. Caregivers reported that physical demands in caregiving increased substantially during the last three months of the care recipient’s life. As family caregivers provided more assistance in ADLs, they were at greater risk of reporting high caregiver burden.
Hodgson, Higginson, McDonnell and Butters prospectively collected patient and family well-being data on all patients referred for care over a six-month period in six home care services in Ireland. Five hundred and eight patients died while in care; 75% of these patients died at home. At referral, 32% of families had severe or overwhelming anxiety. During the last week of care, anxiety remained severe for 26% of care givers. Patient and family well-being were inter-related and there were significant interactions between family anxiety and patient physical and psychological symptoms and communication. Family anxiety at referral strongly predicts family anxiety at last week of life. Excluding family anxiety at referral, other predictors for family anxiety were patient symptom control, sex of patient, diagnosis, and patient age. These data suggest that while severe anxiety is not inevitable for all family members caring for a terminally ill patient, patient characteristics play a role in predicting family anxiety. Family anxiety is associated with patient age, sex, diagnosis and physical symptoms.

Outcomes at Transitions (Placement or Death)

Eight studies reviewed investigated the impact of two critical transitions faced by many caregivers (nursing home placement or the death of the care recipient) on caregivers. Some of these studies overlap with the topic of bereavement, which we did not explicitly address. We include only those studies that were also relevant to understanding other caregiver burdens. One overall impact of these was highlighted previously (under Satisfaction). Collins et al. prospectively examined changes in depression among family caregivers to dementia patients at three “transition” periods: nursing home placement, bereavement, and continuing residential care over three time periods (pre-event, and two post-event points). A convenience sample of family caregivers (n=142) was included in the analysis focusing on depression (n=46 residential caregivers, 49 institutional caregivers, and 47 bereaved caregivers). The mean depression levels for the total sample declined slightly over the three measurement periods but did not reach statistical significance. Depression appeared to decline among male caregivers and for bereaved caregivers over time but this change was not statistically significant. A more complex relationship occurred between gender and transition groups. Female residential and female institutional caregivers had higher combined levels of depression over time than female bereaved caregivers. In contrast, male residential and institutional caregivers had lower depression than bereaved male caregivers. Finally, male institutional or residential caregivers had significantly lower depression than their female counterparts. Thus, gender has an influence on mental health outcomes for caregivers who continue to provide care as well as those experiencing bereavement.

Grant, Adler et al. prospectively examined the extent to which the chronic stress of AD patient caregiving was alleviated by placement or death of the patient in 119 caregivers and 48 non-caregiving comparisons. Three assessments on caregiver mood, blood pressure, and symptoms were conducted at six-month intervals among caregivers who cared for the dementia patient at home for all three observations (n=38), who placed the patient at follow-up (n=28), whose spouse were placed and subsequently died (n=27), those whose spouses died at home (n=26), and 48 non-caregiving spouses. Caregivers who placed the patient in a nursing home or whose care recipient died showed significant improvement in depressive and physical symptoms at 6 and 12 months after the transition (placement or death) compared to caregivers who continued to provide care and the non-caregiving comparison group, both of whom had relatively stable depression scores over time. Caregivers who placed the patient at the later time reported fewer serious symptoms over time compared to no change in the other groups.
However, both placement and death of patient were associated with higher blood pressure during transitions, and this continued up to 12 months after the transition. These data suggest that both placement and death of the demented relative can have beneficial effects on the mood and serious symptoms of the caregiver but that this effect can take 12 months to become evident. The blood pressure data suggest that a lengthy period of physiological readjustment may be necessary after placement or death of the AD spouse.

Hays, Kasl, & Jacobs\textsuperscript{276} prospectively examined depression, anxiety, and distress in 1,112 caregivers with seriously ill spouses who survived or died over a two-year period. For analysis, the sample was divided into five groups, depending on whether the subject’s spouse had been hospitalized for a critical illness or elective surgery, whether the outcome of the illness was death, and when the death occurred. Depressive symptoms and feelings of helplessness/hopelessness were higher in caregivers whose spouse was hospitalized for critical illness, regardless of the outcome. In addition, distress related to the incidence of bereavement was significantly higher than that of the control group and endured for at least six months after the spouse’s death. Anxiety levels did not change in response to either transition (hospitalization and/or death). Depressive symptoms and general anxiety were higher among widows and wives at the time of hospitalization compared to males while gender differences disappeared at two and six months for all bereaved caregivers, regardless of gender. Middle-age subjects reported more hopelessness/helplessness at baseline and six months compared to elderly subjects.

Schulz, Mendelsohn, Haley et al.\textsuperscript{277} prospectively examined the type and intensity of care provided by 217 family caregivers to persons with dementia during the year before the patient’s death and assessed the caregiver’s responses to the death. Overall, caregivers exhibited high levels of depressive symptoms while providing care to the relative with dementia (mean CES-D score: 15.8\(\pm\) 11.7; median, 13). Forty-three percent of caregivers had scores above 15. At the death of the relative, depressive symptom scores spiked to 22. However, within three months of the death of the relative, caregivers had clinically significant declines in the level of depressive symptoms, declining to a level similar to pre-bereavement levels (mean, 16.2\(\pm\)12.3; median, 14). Within one year the levels of symptoms were substantially lower than at baseline (mean 11.5\(\pm\)9.4; median, 9) (p=0.03). Caregivers who cared for and then placed their relative in a nursing home had mean scores for depression of 17.1\(\pm\)11.9 (median, 15) before placement and mean depression scores of 18.1\(\pm\)13.0 (median, 15) after placement. One year after placement, depression scores remained high and were significantly higher among caregivers of patients who had been institutionalized than among those caregivers of patients who had died (mean, 16.2 vs. 11.5; median, 14 vs. 9; p=0.02). Use of antidepressant medication and anxiolytic drugs increased after the death of the relative (16.6% and 19.4% before the death, 21% and 18% after the death). While the death of a close relative is generally viewed as a powerful source of psychological stress, the caregivers in this study showed remarkable resilience in adapting to the death of their relatives.

Volicer, Hurley, and Blasi\textsuperscript{278} conducted a survey of a nationwide sample of 156 family caregivers of demented individuals who had died during the preceding year. Twenty-two percent of patients died at home. The results indicated that end-of-life experiences of individuals with dementia differ according to setting of care. Patients cared for at home and receiving hospice care during the last 90 days had fewer symptoms vs. other groups and fewer signs of physical distress during the dying process. Hospice use did not affect caregiver burden but these patients stayed at home 23 days longer and were twice as likely to die at home than in an institution.
Caregivers of patients dying at home had increased time dependence burden but other burden scores were similar among all groups. Caregivers with patients dying both at home and in an institution were less satisfied with care than those cared for in only one setting. No effect on burden was found for use of formal or informal assistance. Psychiatric symptoms in the patient increased caregiver burden and were the most common cause of institutionalization. Receipt of psychiatric care was associated with longer stay at home. Presence of advance directive decreased hospital stays and increased the likelihood of dying in a nursing home. These results indicate that quality end-of-life dementia care can be provided at home by family, with hospice and psychiatric care.

Martikainen and Valdonen\(^2\)\(^7\)\(^9\) prospectively examined the effects of the death of a spouse on caregiver mortality using census and death certificate data on all Finns who died between 1986 and 1991. Five thousand five hundred deaths of widowed individuals were examined to determine if income and education mitigated the negative effects of spousal death. The results indicated that both men and women experience excess mortality after the death of a spouse and that the relative excess mortality among the bereaved is broadly similar in all education and income subgroups analyzed. The absolute mortality difference between widowed and married persons, however, tends to be larger among less educated and, especially, low-income persons.

Markowitz, Gutterman, Sadik, and Papadopoulos\(^2\)\(^8\)\(^0\) investigated the relationship of caregivers’ health-related quality of life to the burden of caring for patients with Alzheimer disease and resource utilization in a sample of 2,477 dementia caregivers. Compared with a normative, age-adjusted sample, the dementia caregivers had lower mental and physical scores (for the latter, only those 54 years of age or older). Increased caregiver mental functioning was associated with caregiver support and perceived quality of patient care, fewer hours of caregiving, and fewer patient behavioral symptoms.

### Caregiving for Non-Cancer, Non-Alzheimer’s Disease

There has been little research done on palliative caregiving and non-cancer deaths, other than in patients and families with dementia. Two studies reviewed examined the needs of terminally ill non-cancer patients and their caregivers. McCarthy, Addington-Hall, and Ley\(^2\)\(^8\)\(^1\) examined the needs, services, and outcomes of care for 600 non-cancer deaths (heart disease) from the Regional Study of Care of the Dying, a population-based investigation of dying people based on reports of their main informal caregivers after the death. Just under half (47%) of caregivers felt they had not been able to get all the information regarding the deceased’s illness that they had wanted or when they had wanted it. Thirty-seven percent of caregivers said they had known the deceased was likely to die and 26% said they had “half-known,” whereas 26% of deceased patients were reported to have known and 25% were reported to have “probably” known that they were likely to die. Of those deceased patients who were reported to have known or probably known they were likely to die, most were reported to have had to work this out for themselves: only 8% were said to have been told by a GP or hospital doctor. Moreover, only 44% of caregivers were told of the terminal prognosis. Half of the patients (54%) died in hospitals, 30% at home, and 4% in other places. Patients under age 75 were less likely to die in an institution and more likely to die at home than patients 75 or older. Women aged 75 or older more frequently died in residential or nursing homes than males. One-quarter of the deceased were reported to have expressed a wish to die sooner; more women than men were said to have expressed such a wish (30% vs. 17%, \(p<0.01\)). Moreover, decedents who were aged 75 or older were 2.6 times more likely to have expressed a wish to die sooner; those with four or more
symptoms perceived as “very distressing” were 2.3 times more likely; and those who had a poor quality of life wee 1.9 times more likely to expressed such a wish. These results indicate that healthcare providers rarely discussed prognosis with heart disease patients, even though the five-year survival rate of chronic heart disease is about 50%, comparable with many types of cancer. Better palliative care, with concern for symptom control and psychological care should be available to all dying patients. Open communication about death and dying is needed to allow for a patient-centered end of life.

Evangelista, Dracup, Doering et al.\textsuperscript{282} surveyed 103 heart failure patient/caregiver dyads to investigate whether caregiver characteristics were related to the emotional well-being of heart failure patients. Overall, patients had significantly lower (poorer) emotional well-being scores than caregivers (p<.001). However, both gender and age influenced well-being. Female patients and caregivers had lower emotional well-being compared to males; however, the difference was only statistically significant for patients (p=<=.018). Male and younger patients had higher (better) scores than female and older patients (p<.05). Patients’ age, gender, and caregivers’ emotional well-being accounted for 54% of the variance in patients’ emotional well-being. These findings suggest that caregiver emotional well-being is associated with the well-being of the heart failure patient. A focus on supporting caregivers and providing them with methods to support their loved ones would be beneficial to patients.
E. Key Question 2 and 3.

2. What patient, family, and healthcare system factors are associated with better or worse outcomes at end of life?

3. What processes and interventions are associated with improved or worsened outcomes?

Elements associated with healthcare system performance, especially continuity of services

Introduction

We used a multidisciplinary systematic review of the overall literature on continuity of care as a conceptual framework for our review. Based on a systematic review of the literature through 2001 and feedback from an expert workshop, these investigators defined continuity as “the degree to which a series of discrete healthcare events is experienced as coherent and connected and consistent with the patient’s medical needs and personal context.” This review, and a second systematic review particularly interested in the concept of measurement, identified several key elements of continuity across disciplines: informational, management, and relational. Although we make distinctions between these aspects of continuity in an effort to bring some clarity to the literature in our discussion, in practice, interventions and their measures overlap these boundaries to varying degrees.

We evaluated nine systematic reviews that potentially dealt with the subject of continuity. All nine addressed the project questions and met implicit quality criteria. We went beyond the systematic reviews by including other interventions to improve continuity at the end of life published after these systematic reviews or published at any time if not already addressed in a systematic review. In total, we reviewed an additional 20 intervention studies. Because reviews and interventions related to heart failure were distinctive, we discuss them after more general interventions targeting continuity.

The remainder of this section summarizes the systematic reviews, meta-analyses, intervention, and observational studies relevant to continuity of care. With regard to observational literature, we identified prospective, observational cohort studies addressing continuity and that also presented data separately by race, selected disease cohorts, or selected sites of care. Because there were so few studies that met the design criteria, we also identified several other of the largest studies that addressed important aspects of those questions. Nineteen observational studies met these criteria. All observational studies are discussed at the conclusion of this section. We first summarize information related to continuity in general, and then a series of reviews and studies of patients with congestive heart failure. Summaries of the association of patient, family, and health system factors to continuity and the effectiveness of interventions in improving continuity are found at the conclusion of Chapter 3.
Systematic Reviews

We found seven systematic reviews (Table 6). These systematic reviews are briefly summarized in Tables 6 and 7 and discussed in the text in more detail. Two of the reviews and a published paper (by the same authors) graded and summarized other systematic reviews.

Table 6. Systematic Reviews for Continuity/Coordination

<table>
<thead>
<tr>
<th>Study</th>
<th>Issues Addressed</th>
<th>Date Search Concluded</th>
<th>Date of Publication</th>
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<tr>
<td>Gysels, 2004</td>
<td>Continuity/coordination, Palliative care</td>
<td>March 2003</td>
<td>Unpublished</td>
</tr>
<tr>
<td>Higginson, 2001</td>
<td>Home death rate as outcome</td>
<td>1999</td>
<td>2001</td>
</tr>
<tr>
<td>Higginson, 2003</td>
<td>Palliative care</td>
<td>2000</td>
<td>2003</td>
</tr>
<tr>
<td>Wilson (Health Canada)</td>
<td>Continuity, case management</td>
<td>October 2003</td>
<td>Unpublished</td>
</tr>
</tbody>
</table>

Gysels et al., the review that explicitly addressed the issue of coordination, identified 11 relevant individual trials. Ten experimented with organizational changes in the usual available care. Many of these studies address palliative and home care interventions and are also addressed in systematic reviews on these topics. Not all studies in Gysels et al. or Wilson (Health Canada) were relevant to the end of life, so relevant interventions have been extracted and non-cancer or more recent interventions have been added.

With regard to improving continuity, we identified an extensive systematic review of the literature on improving supportive and palliative care for adults with cancer. It found that specific interventions, such as structured symptom assessment, needs assessments, improved medical record documentation and sharing, coordination of services, information or education, support, and preparing patients for physician visits, may all improve utilization or various patient-centered outcomes or utilization. Multi-component interventions including these and other elements, such as home care, care protocols, nurse availability, team care, and involvement in discharge planning, often as a part of a palliative care intervention, have also shown some evidence of effectiveness. However, a meta-analysis found that benefits of palliative care interventions, although affecting several domains, appear to be relatively small. Multi-component interventions are often not targeted toward particular outcomes but attempt to address multiple domains, and are also often ill defined. Nevertheless, these studies provided some evidence for reduced hospitalizations from these interventions. The review recommended that further intervention research describe theoretical models, attempt to separate out effects of different components, and evaluate the processes of care in order to better understand how interventions affect outcomes.

Palliative care, home care, and hospice interventions include continuity as an integral component. These interventions vary greatly in the composition of the team and nature of the
Some of the systematic reviews assessed communication interventions, support of chemotherapy, and primary care. A meta-regression reported that palliative care had small benefits in many areas but did not show benefits for home death. Results were consistent by the type of service. Less evidence is available for hospital at home.

Table 7. Summary of Results from Systematic Reviews Relevant to Continuity

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Results</th>
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| Record continuity (patient-held records) | 3 studies (including 2 RCTs) evaluated this type of intervention. 1 RCT was extremely small (only 21 patients completed). No clear benefits except for patient-reported use.
| Management continuity | |
| Use of protocols/pathways/guidelines | Only 2 studies (both observational and without control groups) evaluated those relevant to the terminally ill. |
| Nurse coordinator/case manager | 11 studies identified (although end-of-life relevance of many is unclear) (4 RCTs). Results of studies were conflicting, but studies were very heterogeneous. Also see CHF section below for disease-specific reviews and interventions on this issue. |
| Relational continuity | All showed small benefits in a number of outcomes, but not home death. |
| Home palliative care | 22 studies |
| Hospital-based palliative care | 9 studies |
| Integrated inpatient hospice/home care and hospital advisory | 6 studies |

A systematic review of case management at the end of life used the Case Management Society of America’s definition of case management, “a collaborative process which assesses, plans, implements, coordinates, monitors, and evaluates options and services to meet an individual’s health needs through communication and available resources to promote quality, cost-effective outcomes.” Eleven research articles were selected for review out of “over 200” identified, although it is unclear how they defined relevance. The applicability of this descriptive review to this report is unclear because studies of different quality were mixed together, many of the included studies do not seem relevant to the end of life (for example, patients with early Alzheimer’s dementia or discharges from a general medical service), and few articles overlapped with our review. In the potential patient-related domains identified with the review, they found conflicting results for well-being and quality of life, patient satisfaction, hospital utilization, home death, and cost-effectiveness. Impact on family caregiver burden was promising but still had limited impact. In general, although they found anecdotal accounts of end-of-life case management, few research articles compared case management to other delivery models, and end-of-life populations or issues were often not included.

A systematic review using only the word “continuity” with end-of-life terms found 13 relevant research articles, 6 monographs, 14 non-research articles, and 2 primary websites.
The review was very limited because of the single search term, and articles were almost all observational and quite heterogeneous.

**Additional Interventional Studies and Continuity**

**Information/record continuity**

The SUPPORT intervention\(^{287,288}\) and other studies that focused mainly on advance care planning are fully described in that section. Latimer et al.\(^{229}\) randomized 61 patients to a patient care traveling record, and did report a marginally significant improvement in pain control (described in the Pain section above). An RCT giving patients audiotaped recordings of their multidisciplinary oncology consultations reported only higher “usefulness” of the clinic (described in detail under the Satisfaction section above).\(^90\)

**Management continuity**

We identified two studies examining the effects of ethics consultations in the ICU.\(^91,289\) The second study was a multi-site trial based on the earlier study in a single institution. Although the interventions were not standardized across institutions, in general, ethics consultations involved coordinating care by interviewing “those involved in the patient’s care who bore on the issues under consideration.” Issues were framed in easily understood ethical terms with the involved parties; consultations and recommendations were documented in the medical record; and ethics consultants provided ongoing follow-up. These studies reported that, only in the subgroup of patients who did not survive to discharge from the hospital, patients receiving the intervention had fewer hospital and ICU days and days receiving ventilation than patients in the control group. Further details of these studies are described in the Satisfaction section.

Another study in the ICU reported that patients cared for by an attending physician who focused on continuity of care had lower lengths of stay than other patients in the ICU.\(^290\) This single site quality improvement report involved two ICU clinical nurse specialists and an ICU physician who adhered to a structured communication with the family and the nurse specialists who also provided psychosocial support to families. The Jadad score for this study was 0.

A multi-site RCT of team-managed home-based primary care in the VA\(^{147}\) focused on continuity and reported results separately for terminally ill patients. The study reported improvements in multiple domains and is described in detail in the Satisfaction section. Another RCT of nurse coordination in the community, described in the Satisfaction section, reported no effect in multiple domains.\(^242\)

An RCT of hospital-at-home reported no difference in the location of death (58% controls, 67% intervention) in an intent-to-treat analysis.\(^291\) Hospital at home provides practical home nursing support continuously for up to two weeks, typically at the very end of life. However, only 61% of patients offered admission to the home hospital actually enrolled; among those who used hospital at home, the frequency of home death was higher (78% vs. 58%). In addition, this RCT compared the service to standard care, which included a variety of hospice and cancer support services. The Jadad score for this trial was 2. An RCT of a hospital palliative care team, described in the Satisfaction section, did not report an effect on satisfaction.\(^85\) A pre-post comparison of a Kaiser Permanente palliative care program, also described in the Satisfaction section, also reported significant improvements in satisfaction.\(^87\)
DeCourtney et al. developed a multidisciplinary quality improvement intervention to deliver end-of-life care services to remote Alaska Native communities, and in a pre-post evaluation of site of death records reported that home deaths had increased from 33% in 1997 to 77% in 2001. This approach (Helping Hands) relies on nurse case management in extremely remote villages and includes coordination with remote physicians, bush air support for nurse visits and medical supply provision, and remote communication using radio and phone. It mobilizes village youth to provide practical hands-on support to patients and families when medical professionals are not available.

Raftery et al. performed a randomized controlled trial in the UK of the cost-effectiveness of a district coordinating service for terminally ill cancer patients. The nurse coordinators were based in the community; their role was to assess the need for different services, advise on how to obtain services or contact the agencies themselves when needed, and ensure that services were provided and of good quality. They acted as liaisons with other nurses but did not provide any clinical care themselves. Outcomes were all related to costs. The intervention did reduce health service costs, hospital days, and nurse home visits but did not affect indirect or direct costs borne by patients. The Jadad score for this study was 2.

Selwyn et al. evaluated the impact of a multidisciplinary palliative care consultation service for patients with AIDS in an urban teaching hospital in an uncontrolled pre-post design. One of the components of this program includes coordinating care with primary HIV providers and community support and healthcare resources. They report follow-up data on 115 patients followed until death or problem resolution by an interdisciplinary team that worked across settings and attempted to integrate palliative care with usual AIDS care. Full problem resolution was 73% for care decision-making, 59% for conflict resolution, and 7%–67% for symptoms from the MSAS. 55% died while in care, 29% went to a nursing home with hospice, and 14% went to a nursing home for chronic care.

Stockelberg et al. evaluated the impact of home nursing for 17 patients with hematological malignancies, and found that providing support and transfusions in the home avoided most ambulatory visits.

We identified two RCTs of continuity-related interventions for the frail elderly. Melin et al. conducted a study of elderly patients who had from 1-5 ADL impairments. Intervention and control patients had a variety of diagnoses and a mean age of approximately 80. Intervention consisted of a team of physicians and nurses who made regular home visits for assessment and treatment as well as 24 hour phone support. Approximately 25% of the 249 patients (150–I, 99–C) died during the study. Relative to controls, the intervention group improved in IADL, social activities, and more were living at home at the conclusion of the study (79% vs. 63%). Hospital use was similar, but controls had more long-term care use and intervention patients used more home care days.

Mann et al. conducted an RCT of 104 home-based frail elderly patients (52–I, 52–C) who were randomized to functional and home environmental assessment. These patients averaged 73 years of age and approximately 60% in both groups had been hospitalized in the previous six months. Intervention patients received assistive devices such as canes or walkers and environmental interventions such as ramps. Control participants declined on 7/9 functional measures during six months of follow-up compared to the intervention group. Pain scores were also lower at the conclusion of the trial in intervention group. There was no difference in total
costs—although intervention participants spent more on devices and modification, and control
groups spent more on nursing homes and nurse visits.

**Relational continuity**

In a randomized, crossover trial, 214 patients receiving palliative chemotherapy completed a
HRQOL questionnaire at three successive outpatient visits. Physicians and patients were
briefly educated about the intervention and were given a graphic summary of the questionnaire
before each consultation. HRQOL-related issues were discussed more frequently in the
intervention than in the control group, and physicians identified more patients with moderate-to-
severe problems in feelings, social activities, and fatigue in the intervention than in the control
group. Significantly more patients in the intervention group than in the control group received
counseling from their physician on managing their health problems, the level of patient
satisfaction with emotional support was higher, and significantly more patients showed
improvement in mental health and role functioning. Seventy-nine percent of patients believed
that the HRQOL summary increased their physician’s awareness of their health problems. The
Jadad score for this study was 3.

**Specific populations**

**Heart failure**

Many of the studies discussed in this area (in the context of systematic reviews or
interventions) excluded ‘terminally ill’ patients and did not address other palliative domains.
However, because these studies enrolled patients with advanced CHF who had high mortality
and given the prognostic uncertainty in this condition, we determined them to be relevant for the
purposes of the review. We identified five systematic reviews related to continuity and
coordination in heart failure. One was a previous review that has now been updated and one
older review only included articles; these are not included here. These reviews all addressed
the literature somewhat differently, with different definitions and inclusion criteria but some
overlap; they are summarized briefly in the table below.

<table>
<thead>
<tr>
<th>Study</th>
<th>Issues Addressed</th>
<th>Date Search Concluded</th>
<th>Date of Publication</th>
</tr>
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<tbody>
<tr>
<td>Phillips, 2004</td>
<td>Comprehensive discharge planning plus post-discharge support</td>
<td>2003</td>
<td>2004</td>
</tr>
<tr>
<td>McAlister, 2004</td>
<td>Multidisciplinary management programs (specialized multidisciplinary teams, enhancing patient self-care, and telephone contact)</td>
<td>2003</td>
<td>2004</td>
</tr>
<tr>
<td>Windham, 2003</td>
<td>Care management for older patients</td>
<td>2002</td>
<td>2003</td>
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In general, these reviews concentrated on utilization outcomes and mortality. McAlister et al.’s review of 29 RCTs\textsuperscript{300} reported that trials that incorporated follow-up by a multidisciplinary team, enhancing patient self-care activities, or used telephone contact and advised patients to see their physician when needed all reduced heart failure hospitalizations. Reductions in mortality and all-cause hospitalizations were more variable. All interventions incorporated patient education.

Results for patient-centered outcomes were more equivocal. Windham et al.\textsuperscript{302} and McAlister et al.\textsuperscript{300} reported that approximately half of studies that examined HRQOL or functional status showed improvements. Phillips et al.\textsuperscript{299} pooled QOL scores for 6 RCTs and reported a statistically significant difference: 26\% improvement in the intervention groups compared to 14\% in the control groups. Patient satisfaction was measured in only three of 32 studies evaluated in one review.\textsuperscript{301} One review descriptively compared the characteristics of the 15 effective to the 17 ineffective case management interventions and concluded that education and close monitoring for CHF symptoms by nurses or care managers were important components. Eight of the 32 studies included a social worker as part of the intervention.\textsuperscript{301}

**Additional Interventions Studies and Continuity in CHF**

We identified seven additional interventions related to continuity and coordination in CHF.\textsuperscript{303-305,306-309,310}

Stewart et al. reported the outcome of a nurse case management intervention that included structured, intensive education, both patient and family activation, and coordination of care activities between both the primary physician and cardiologist.\textsuperscript{303,311} Twenty deaths (10\%) occurred in six months of follow-up. Rates of unplanned readmission were lower in the intervention group 68 vs. 118, p=0.031), and costs were correspondingly lower. Quality of life improved among survivors in both groups. The investigators reported the effectiveness of the intervention on the most high risk patients and noted a mortality benefit as well in this subset analysis.\textsuperscript{311} The Jadad score for this trial was 1.

Goldberg et al. randomized CHF patients to either a telephonic monitoring system linked to an electronic scale and trained CHF nurse case manager vs. usual care.\textsuperscript{312} Patients with prognosis < 6 months were excluded as were those with advanced renal disease (dialysis or Cr. > 4.0) and other specific cardiac conditions although 13\% (37/280) of enrolled patients died in six months of follow-up (lower in the intervention group 8\% vs. 13\%). There was no difference in re-hospitalization and quality of life improvements were similar in both groups. The Jadad score for this trial was 1.

Jaarsma et al. randomized 179 patients (84–I, 95–C) to a nursing education and one time telephone follow-up of CHF patients that was intended to increase self-care during the ten days after hospital discharge.\textsuperscript{307} Exclusion included serious comorbidity. In nine months of follow-up, 38/179 (21\%) patients died. Self-care behaviors attenuated strongly in control and intervention patients after discharge, although there was a small difference in persistence of self-care behaviors at nine months. This study failed to show a difference in utilization. The Jadad score for this trial was 1.

Philbin et al. conducted a hospital-level quality improvement cluster randomized trial.\textsuperscript{313} Five intervention hospitals attempted to implement a critical pathway for CHF management. The intervention also included staff professional education. CHF survivors were followed for six
months post-hospitalization. All-cause mortality in these patients averaged about 20% among survivors at six months. This inpatient-only intervention noted no post-discharge benefits on mortality, utilization, or quality of life. The Jadad score for this trial was 1.

Goodyer et al. performed an RCT of a three-month intensive medication counseling intervention in patients with chronic, stable heart failure. The study did not report mortality. The intervention significantly improved compliance and decreased edema and subjective breathlessness in the intervention group compared to the control group. The control group also had significant decreases in scores for energy and physical mobility that were not seen in the intervention group. The Jadad score for this trial was 1.

Heidenreich et al. reported an uncontrolled pre-post evaluation of an automated weight and vital signs monitoring device linked to physician and nurse manager alerts coupled with nurse education. Forty percent of these patients had moderate or greater reduction in left ventricular function. Survival was estimated as 82% at 12 months. Pre-post utilization and costs were lower in the intervention group, although quality of life was unchanged.

Gorski and Johnson reported a post-evaluation of a quality improvement intervention without a control group that suggested benefits in self-care and utilization.

Observational Studies in Continuity

With regard to the association of ethnicity with continuity, although a prospective cohort study found that blacks received less intensive care in the hospital, others have found that black nursing home residents tend to receive higher-intensity care and are more likely to die in the hospital. Several studies provide potential explanations for these disparities. One study found that black residents tend to be concentrated in nursing homes with fewer available resources, which is associated with more hospitalizations. Another study examining non-English-speaking patients found that patients of different ethnicities had poorer understanding of their prognosis than English-speaking patients. Another found that nurses spent less time at the bedsides of non-white dying patients.

In related literature about settings of care and continuity, we identified several studies that identified problems related to transitions in care in nursing homes. Other observational literature (see Satisfaction and Advance Care Planning) highlighted the challenges of transitions and/or continuity involving other or multiple settings. This literature also highlights the possible role of advance care planning (ACP) in reducing transfers. One study highlighted an association between more intensive staffing and primary care in nursing homes and decreased risk for transfers. Several studies suggest a higher preference for death at home than is typically observed.

With regard to disease, the observational literature underscores the risks of discontinuity in patients with CHF. One study highlighted the social factors, especially single marital status associated with a risk for re-admission. Several other studies demonstrate that the risk of re-admission (up to 50%) is particularly associated with age and comorbidity, and in such unselected patients is even higher than in trials using more selected patients conducted in CHF. We found no studies of other particular disease states or comparative studies of risk by disease.
We identified several studies notable for particular mention related to the subject of continuity. Fisher et al.’s large national study of Medicare cohorts (described in the Satisfaction section above) descriptively highlighted the fact that ten or more physicians were involved in the care of 37% of chronically ill patients during the last six months of life.\textsuperscript{115} A retrospective study of approximately 9000 decedents using administrative data demonstrated a strong association between higher physician primary care continuity measured using the Modified Continuity Index (MMCI) and lower emergency department use in the last six months of life as well as greater likelihood of home death.\textsuperscript{328,329}
F. Key Questions 2 and 3:

2. What patient, family, and healthcare system factors are associated with better or worse outcomes at end of life?

3. What processes and interventions are associated with improved or worsened outcomes?

Elements associated with decision-making, especially advance care planning

Advanced directives (ADs) (including “living wills” and “instructional directives”), are formal, legally endorsed documents that state instructions for care (e.g., circumstances in which life-sustaining treatment is to be provided or forgone) or that name a proxy/surrogate decision-maker (e.g., “durable power of attorney” and “healthcare proxy”) in the event of future decisional incapacity. The federal Patient Self-Determination Act (PSDA) (OBRA-1990) and legislation on practice in all 50 states provided legal enforcement for ADs that followed certain procedures. More recent efforts to elicit patient preferences have moved toward advanced care planning, which denotes a broader set of activities. Advance care planning requires a well-informed patient or surrogate to make decisions about future care so that treatments undertaken during a future period of decisional incapacity will still be in accord with the patient’s preferences.

For this report, studies involving advance-care planning, advance directives, living wills, and “do not resuscitate” (DNR) orders were included if their targets were patients or families (rather than only reporting about clinicians). We evaluated four systematic reviews that potentially dealt with the subject of ACP. We went beyond the systematic reviews by including other interventions to improve ACP at the end of life published after these systematic reviews or published at any time if not already addressed in a systematic review. In total, we reviewed an additional 21 intervention studies. All observational studies that met our criteria are discussed at the conclusion of this section.

The remainder of this section summarizes the evidence from systematic reviews, intervention studies, and observational studies relevant to advance care planning, including ADs, living wills and DNR orders. Summaries of the association of patient, family, and health system factors with ACP and the effectiveness of interventions in improving ACP are found at the conclusion of Chapter 3.

Systematic Reviews

Four systematic reviews were identified that met implicit quality criteria (see Table 9), and reflected three separate reviews addressing the topic of advance care planning.
<table>
<thead>
<tr>
<th>Study</th>
<th>Aspect of Advance Care Planning</th>
<th>Date Search Concluded</th>
<th>Date of Publication</th>
</tr>
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<tbody>
<tr>
<td>Baggs330</td>
<td>End-of-life care decision-making</td>
<td>2000</td>
<td>2002</td>
</tr>
<tr>
<td>Hanson et al.331</td>
<td>Interventions targeting patients, physicians or both, by their effect on increasing use of patient preferences and reducing use of life-sustaining treatments</td>
<td>1996</td>
<td>1997</td>
</tr>
<tr>
<td>Higginson et al.332</td>
<td>Communication, advance care planning, continuity</td>
<td>1999</td>
<td>2002</td>
</tr>
<tr>
<td>Walsh et al.333</td>
<td>Patient satisfaction, patient preferences</td>
<td>1997</td>
<td>1998</td>
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In the first of these, Baggs330 systematically reviewed the literature for evidence on end-of-life care for older adults (over 44 years old) in ICUs and their families and caregivers, focusing in part on literature involving nursing. Ninety-one studies were evaluated, reviewing the literature on interventions, prospective cohort studies, and retrospective analyses. Baggs’ review found that the characteristics of appropriate care for dying patients, particularly patients with DNR orders, are not clear. She also identified that advanced age, severity of condition, and DNR orders correlate with limited life-sustaining treatment. Two studies found that resource use decreased following placement of DNR orders. One study found that life-supporting interventions were withdrawn or withheld in 45 percent of ICU patients before their death. On the whole, age was not a factor in limiting care among patients once admitted to the ICU, but age has been a factor in limiting admission to the ICU for the elderly and some studies showed that the elderly appear to receive less aggressive care than do younger patients.

Furthermore, Baggs’ review showed that end-of-life hospital care often involves inadequate communication and disagreement between patients and their families and physicians and nurses. Several studies, including the SUPPORT study, found that families and clinicians often have an incomplete understanding of patients’ preferences. This inadequate communication can cause some elderly to receive technical interventions rather than their preferred comfort care prior to death. Since dying ICU patients are generally not capable of communicating their preferences, achieving accord on a plan of care is often challenging. Ongoing communication is important because many patients want relief of symptoms without prolonged dying, decision-making that requires both families and providers, and psychological support. Communication is important because, while some of those in ICUs experience a feeling of safety and security, many experience discomfort, cognitive impairment, and anxiety. In the SUPPORT project,287 families reported that in the last three days of life, dying patients were most often in pain, experiencing dyspnea and fatigue. Baggs’ review of clinical interventions also showed that hospital end-of-life care does not rely upon evidence-based guidelines.

The Hanson et al.331 systematic review examined the literature between January 1990 and March 1996, on whether interventions aimed at physicians and/or patients affected AD completion and subsequent end-of-life care. Six of the eight randomized studies reviewed, each targeting only patients, increased the rates of AD completion or proxy choices when they
combined written materials on ADs with one or more discussions with physicians or a social worker about ADs. Five other studies, that targeted only physicians in single sites, used physician education in combination with reminders and feedback. This combined approach was successful in increasing AD completion and/or advance care planning discussions with patients. Three additional studies reviewed involved both physicians and patients. For example, SUPPORT showed that having an intervention to improve advance care planning did not alter the use of life-sustaining treatment or other outcomes.  

A systematic review of the literature and meta-analysis by Higginson et al. focused on the impact of hospital-based palliative care teams on patient outcomes and on families. Some of the findings related to advance care planning, particularly reporting a modest effect on hospital length of stay, but the authors note that the study designs do not allow confidence in this assessment or generalization to other settings. The 13 studies incorporated in the Higginson review do not overlap with this report. This Higginson review also reported that hospital-based palliative care teams are somewhat beneficial in terms of reducing the length of hospital stay and having a small positive effect on addressing patient’s symptoms.

In the other systematic review, Walsh et al. examined the literature on conveying “bad news” concerning a life-threatening diagnosis or death, including publications between 1994 and August 1997. Ten RCTs examined how bad news is delivered and how the impact in doing so influences patients’ knowledge of their diagnosis, psychological adjustment, and satisfaction. In eight RCTs, the impact of communication interventions on patient recall and information needs was inconclusive; half showing an increase in short-term knowledge and the others showing no effect. Of the eight RCTs examined for the effect of communication practices on psychological adjustment, seven reported no significant differences, but one RCT found lower adjustment levels and higher anxiety after receiving the “bad news” intervention. The authors noted that these findings were in contrast to an older meta-analysis of 45 studies that had found a positive effect. Patient satisfaction in six RCTs was also inconclusive; three showing an increase and the other three showing no difference.

Additional Intervention Studies of Advance Care Planning

We found an additional 21 intervention studies that were not discussed in the systematic reviews. A trial of ACP in nursing homes was discussed above in the Satisfaction section. Studies varied in scope, methodology, duration, and outcome. These studies involved the following approaches to research involving advance care planning: 1) providing education about and the opportunity to complete an advance directive or participate in ACP discussions to patients; 2) having clinicians, patients, and families/surrogates discuss the patient’s treatment preferences and prognosis for patients who are dying or are likely to die; 3) having clinicians receive consultations to assist their decision-making process with patients; and 4) determining if efforts to document ADs affect treatment. Of these 21 studies, six were RCTs. Two of the RCTs examined ACP discussions in hospitals, three in outpatient settings, and one in nursing homes; the other RCT assessed the impact of physician-initiated AD discussions in elderly outpatients who were not severely ill. Among these studies, the few reporting differences by race/ethnicity and gender are discussed below.
Within SUPPORT, Marbella et al.\textsuperscript{288} examined the accord of patients and surrogates as to the patient’s preferences, comparing the 386 paired patient and surrogate responses of the intervention group for whom trained nurses spent extra time with patients and families to explain and answer questions about prognoses and potential treatments with the 331 patient and surrogate pairs in the control group. No difference in concordance between patients and families followed the intervention. Among all patient-surrogate pairs, there was slightly less accord if the patient was older or the surrogate was not a close family member. Race and gender did not have a significant impact, though the trend was toward more accord in non-white patients and with female patients. The SUPPORT intervention study has a Jadad score of 3.

The Landry et al.\textsuperscript{334} and Dexter et al.\textsuperscript{335} RCTs focused on interventions aimed at increasing the number of adult and elderly patients with advance directives in outpatient settings. In the Landry et al. RCT,\textsuperscript{334} 95 patients with no known life-threatening diagnoses were randomized to the intervention group from the 187 patients in an outpatient clinic. The intervention group participated in an educational seminar without their clinicians and received written materials on ADs, while the control group only received the written materials. AD completion was found to have increased in both groups, but the AD completion rates in the intervention group doubled. In the Dexter et al. RCT,\textsuperscript{335} 1,009 patients age 75 and older, with no known life-threatening illness, were randomized to an instruction directive group, proxy directive group, instruction directive and proxy directive group or to the control group. Primary care physicians were given reminders on the computer-generated encounter form in the patient record to have advance directive discussions with the intervention group patients. Comparatively, there was a significant increase in AD discussions in the intervention groups, half of which resulted in the patient completing an AD. The Jadad score for both studies is 3.

In the Smucker et al.\textsuperscript{336} RCT, 100 patients 65 years or older, in an outpatient clinic, were randomized to physician-initiated discussions on ADs or to discussions on health promotion and assessed on their subsequent emotional or attitudinal response. Patients in the intervention group did not experience adverse emotional or attitudinal effects, and those who had ACP discussions with their primary care clinicians were more satisfied, findings that were even more pronounced when patient’s had higher educational levels and a long term relationship with their physician. This study has a Jadad score of 1.

In a pilot RCT, 61 ambulatory geriatric patients between the ages of 65 to 92 were randomized, either to the control group, which only received a healthcare proxy form, or to the intervention group, which received the form and participated in an ACP discussion with a skilled nurse. For the 31 intervention patients, discussions of ACP involved a program called “Respecting Choices,” while 30 patients had no involvement in “Respecting Choices.” Patients and their surrogates concurred as to the patient’s preferences and more patients opted for less aggressive interventions in the intervention group. Interventions such as “Respecting Choices,” where options are presented along with an actual living will form, have been tested in numerous studies, but generally only at one site of care.\textsuperscript{337} This study has a Jadad score of 2.

We also identified an additional 15 non-randomized intervention studies aiming to improve ACP, six with a comparison group and nine without a comparison group. These studies fell into the following categories: five studies that used specially trained clinicians to discuss ACP, including the diagnosis and prognosis of severely ill ICU patients at high risk of dying with assessment of changes in utilization; three studies that used palliative care teams for ACP discussions for hospitalized patients; one study that used clinician education and
institutionalizing forms to assess patients who died; three studies that provided ACP discussions for patients receiving outpatient care; and three studies of end-of-life discussions in patients with advanced illness receiving non-hospice home care.

In one of the active communication studies in ICUs by Lilly et al., \(^{338}\) advance care planning discussions with dying patients did have some impact, unlike SUPPORT. As part of the intervention, indirect caregivers (e.g., social workers and care coordinators) and some nurses met with the patient following the intensive communication session with direct caregivers, but a standardized meeting template was used to convey information from the intensive communication meetings.\(^{338}\) The improvements documented in the initial intervention were sustained over the ensuing four years. However, this study did not monitor whether the patients admitted to intensive care changed over time. In both of these studies, presenting information about clinical status and expected outcomes to patients having advance directives and their families was associated with increases in decisions to forgo some therapeutic interventions.\(^{338}\)

Similar to the findings of the Schneiderman et al. RCT\(^{91}\) described in the Baggs systematic review\(^{330}\) (and also above in the Satisfaction section), two of the communication studies examined the impact of specially trained teams on changes in utilization prior to death. In the first of these two, clinicians of 31 of 99 ICU patients receiving mechanical ventilation discussed the patient’s preferences and prognosis with a team of two ethical consultants before decision-making became problematic for the clinicians. These consultations resulted in an increase in decisions to forgo life-sustaining treatment and shorter lengths of stay in the ICU.\(^{339}\) In the second study, Campbell and Guzman\(^{340}\) enrolled MICU patients with global cerebral ischemia after cardiopulmonary resuscitation and multiple organ system failure with or without ADs. These patients and their surrogates were given the opportunity to discuss the patient’s prognosis and treatment options with a palliative care team. As a result, patients opted for palliative care more often than for pursuing all possible therapeutic interventions.

The last of this group of ICU communication studies assessed the impact of a healthcare team that met daily to select how 83 ICU patients should be treated, whereupon the team would seek agreement from the family, particularly if it was recommended that treatment be withheld or withdrawn. While the investigators did find an increase in the incidence of withholding or withdrawing treatments, the study did not report whether the withholding or withdrawal of treatment was in accord with the patient’s AD or treatment preferences.\(^{341}\)

Three studies assessed improving communication of patient’s preferences in hospitals and assessing the impact on patient outcomes. Jack et al.\(^{342}\) enrolled 50 cancer patients referred to the hospital palliative care team for symptom control, and compared findings to a control group of 50 patients. Subsequent analysis focused on the positive effect on the patients’ understanding of their diagnosis and prognosis. Patients in both groups improved their understanding of their diagnosis and prognosis, but the intervention group had higher levels of understanding. The Butler et al.\(^{343}\) study assessed the impact of institutionalizing a standardized DNR order form on the number of patients who died in the hospital with a DNR form. Compared to the period before the form was institutionalized (94 patients), there was an increase in the documentation of the 62 patients’ treatment preferences and in patient involvement in treatment decisions while hospitalized. In the Monteleoni and Clark study,\(^{344}\) the impact of a palliative care team communicating with attending physicians about the patient’s treatment preferences was assessed. In assessing rates of feeding tube placement before the time when they initiated their
intervention, the study found no difference in placement of feeding tubes in patients having ADs, including ADs that documented refusal of artificial nutrition.

We found three studies that investigated the impact of ACP communication with patients with advanced illness receiving outpatient care. In a controlled interventional study, the effect of AD education on 50 COPD rehabilitation patients was compared to 43 patients not involved with the educational workshop. Following the AD education, the rate of intervention patients with a completed living will increased from 52% to 72% and the rate with completed durable powers of attorney increased from 34% to 86%, as well as an increase from 16% to 52% in patients discussing their life-support decisions with a physician.345 Another of these studies involved using palliative care consultations for nephrologists caring for 19 patients with no comparison group. These consultations were intended to assist the nephrologists when they helped patients to select treatments, including symptom control and assistance with coping with their burden of illness. These consultations increased discussions of advanced care planning between the patient’s nephrologists and surrogates, though the numbers of advance directives did not increase (also discussed above in the Satisfaction section).88 Both of these studies found that less than half of the patients had ACP discussions prior to the intervention, and their physicians or surrogates did not understand the patients’ preferences.

The third ACP communication intervention in outpatient settings involved 204 patients receiving clinical services from two hospitals. The health status and psychological well-being of all study patients were assessed. Of the 104 intervention patients offered an AD form, 67% completed the AD form. Furthermore, signing the AD form did not adversely affect the patients’ overall health (both physical and psychological).346

From another vantage point, three studies without comparison groups reported facilitating ACP discussion with severely ill home care patients. An evaluation of the Comprehensive Home-based Options for Informed Consent about End-stage services (CHOICES) program, enabled by the comprehensive nature of managed care in Medicare + Choice, 208 enrolled patients with advanced chronic illness elicited treatment preferences (including modifying ADs for patients with ADs), arranged appropriate services, and eventually facilitated entry into hospice care. The focus of CHOICES was to understand a patient’s multifaceted needs and to fashion treatment options to fit the preferences of the patients. During the study period, the length of time in hospice significantly increased among the 208 patients, more patients died at home, and enrolled patients spent less time in hospitals.347 The second home care study investigated the effectiveness of discussions about end-of-life care in a patient’s home. After such discussions, almost all the 84 adult patients with life-limiting illnesses were willing to have an advance directive and wanted end-of-life care at home.348 Both studies facilitated increased utilization of hospice care and dying at home. The third home care study was a small investigation documenting the treatment preferences among 31 AIDS patients with no comparison group. The investigator, who assisted the patients with defining their AD, found that standardized AD forms did not fully capture the patient’s treatment preferences.349
Prospective Cohort Observational Studies on Advance Care Planning

We found an additional 22 prospective cohort studies that were not discussed in the systematic reviews and that address aspects of advance care planning not covered by the aforementioned intervention studies. These employed various methodologies, including using different instruments and respondents. Eight of these were prospective cohort studies drawn from the SUPPORT intervention study. From these studies, three major themes emerge. First, the impact of efforts to increase AD communication, completion, and documentation was evaluated positively by participants, but has not been shown to be effective in altering treatment patterns. Second, patient preferences often change over time and as illness progresses. Third, communicating with families and involving them, as well as patients, in advance care planning is important when possible.

Two SUPPORT studies by Teno et al. \(^{350,351}\) found that, in most instances, ADs did not affect end-of-life decision-making, \(^{350}\) especially when family members and physicians had a clear preference and the patient’s vague advance directive generally disagreed. \(^{351}\) In SUPPORT, the intervention did succeed in having more advance directives present in the medical record, but very few advance directives provided clear instruction that was applicable to the situation. Very few patients and physicians talked about preferences, even when patients actually prefer forgoing resuscitation. \(^{352}\) However, communication and physician understanding of patient preferences improved when physicians have a longer relationship with the patient, have an accurate understanding of the patient’s six-month survival, and discuss resuscitation preferences with the patient. \(^{353}\)

Assuming that clinicians have the responsibility of initiating advance care planning discussions, efforts to help them increase AD communication, completion and documentation have been mixed. Assessment of the impact of the AD discussions among 686 patients initiated by primary care physicians resulted in patients being more satisfied with their physicians, and no significant differences were associated with race/ethnicity and gender. \(^{354}\) One Curtis et al. \(^{168}\) study of 31 AIDS patients also found that, when these conversations did take place, patients were more satisfied, but more so when clinicians knew their patients and their ADs. However, non-Hispanic Whites and those with higher incomes were more satisfied. Furthermore, a study of 642 hospitalized cancer patients found that generalists and oncologists discussed similar topics and demonstrated similar prescribed treatments, which were influenced by the perception of the patient’s preferences and prognosis. \(^{355}\)

Given the importance of patient-physician communication, barriers exist for physicians to initiate end-of-life care discussions. Another Curtis et al. \(^{356}\) study of 57 AIDS patients found that patient-physician communication barriers often stemmed from the clinicians’ lack of education about end-of-life care and lack of time for these discussions, as well as having the opinion that the need for end-of-life care discussions had not been evident. A study of 255 patients in a Swiss hospital found that, even among patients with DNR orders, physicians tended to make DNR decisions when they perceived patients as having a poor quality of life; a perception that is often lower than the patient’s measured quality of life. \(^{357}\)

As time passes, patient’s preferences may change. In a study of 50 adults age 65 and older, selection of health impairment states worse than death were similar to the selection of specific life-sustaining treatment preferences; preferences that did change over time. \(^{358}\) Some of these changes may be associated with specific health events, but the evidence is equivocal. In a study
of palliative chemotherapy treatment decisions in 203 cancer patients, changes in health related quality of life resulted in patients’ opting to modify or discontinue treatment when there was evidence of tumor progression or treatment toxicity; not when the patient’s health related quality of life deteriorated.359 Another study of patient preferences for place of death among 98 cancer patients found that, when patients understood their disease and prognosis, almost two-thirds did not want to die in a hospital and their needs could be met at home.323 Similarly, in a study of 80 cancer patients, patient preferences for information and involvement in decision-making often changed between consultations. Generally, female patients wanted more information than males, and patients with worsening conditions more often wanted physicians to make treatment decisions. Some differences in patient preferences for information were associated with which of the two study physicians was seen on a particular visit, so preferences might well relate to physician behavior during patient-physician communication.360

Over the course of illness, patients’ preferences may also not reflect their actual prognosis or subsequent utilization. Findings from one of the SUPPORT studies found that patients with advanced colon and lung cancer estimated longer survival times than their actual prognoses, and this correlated with a greater likelihood of wanting life-extending interventions.361 Another SUPPORT study found that decisions to withhold or withdraw life-sustaining treatments was not associated with the patient’s race/ethnicity, but those with advanced age and men were more likely to have dialysis withheld or withdrawn.363 Another SUPPORT report found that a patient’s prognosis and preferences appear to affect the timing of documenting DNR orders.364 A related study, assessing hospital utilization among 241 patients with advanced illness, found that patients’ prior preferences were not associated with actual hospital and life-sustaining treatment utilization.365 Similar findings were observed in another study of 65 nursing home residents, where patients’ prior treatment preferences were found not to reflect subsequent utilization, particularly when a patient’s health deteriorated and family and physician chose to limit further interventions.366

The involvement of families in advance care planning and decision-making is also important, but not a standard of practice. In a study of families and friends of 600 heart disease decedents, almost half had limited information on the decedents’ illness, yet half of the decedents were reported as having known their prognosis and likelihood of death—many of whom wanted to die soon because of uncontrolled symptoms.281 In another study of 102 ICU patients in a Paris hospital, physicians did not communicate with half of the ICU patients’ families when they were from another country, spoke a different language, were not the spouse of the patient, and did not have a healthcare background.367 There may be communication barriers among clinicians, between clinicians and patients and their families, and between patients and families. In an assessment of end-of-life care communication and cancer patients in England, Ireland, and Italy, there were communication problems in 30% to 40% of instances between patients and their families, compared to communication problems in 10% to 20% of instances associated between clinicians and clinicians, or patients and their families. There were also more communication problems when patients died in inpatient hospice care, not when patients died at home.104
Additional Cross-Sectional and Retrospective Observational Studies and Advance Care Planning.

Beyond the findings of the intervention and prospective cohort studies, we reviewed an additional 74 cross-sectional observational studies and 57 retrospective studies. Among the cross-sectional studies, we found that 21 had study populations less than 100, 7 reported outcome differences by race/ethnicity, and 23 reported outcome differences by gender. Among the 57 retrospective studies, we found that 8 had study populations less than 100, 11 reported outcome differences by race/ethnicity, and 5 reported outcome differences by gender. The majority of these retrospective studies used large secondary datasets. Among the cross-sectional and retrospective studies, there were significant differences: in study subjects (e.g., health status, diagnosis, prognosis, and proximity to death), setting of care, survey design and data collection instruments, and study methodology. Educational studies have included providing written AD materials or an informational videotape, providing education on the importance of advance directives to patients and/or providers (e.g., using AD discussion guides and written information for consumers, identification of a central or uniform place for the advance directive, and educational seminars), or counseling activities (e.g., supplying written information on ADs and providing an opportunity to complete an AD or assisting patients with life-threatening diseases to make decisions about medical care). Hammes and Rooney\textsuperscript{368} reported remarkable effects from a community-wide implementation of AD education, with 85\% of all who died in La Crosse, WI, having a written AD at the time of death, virtually all of which were available and followed. Showing that at least one large healthcare delivery system can similarly increase the rate of advance care planning, the Veterans Health Care System designated advance care planning for six conditions as being a mandated goal for each of their geographically based networks. The VA system increased advance care planning for veterans with the designated serious illnesses by 15\% system-wide in just three months.\textsuperscript{369} Two recent reports from Oregon where a special form called the Physician Orders for Life-Sustaining Treatment (POLST) is in common use show that three-quarters of all out-of-hospital decedents\textsuperscript{569} and of all nursing facilities\textsuperscript{370} have the POLST completed and available.
G. Summary regarding outcome variations among populations (by patient, family, and health system characteristics)

We identified one systematic review that addressed the issue of outcome variations by race/ethnicity and by settings of care—the two issues that we chose to focus on due to time and resource limitations. Because this review did not map easily to the topics we chose, we discuss it here in introducing a summary of our own findings.

Table 10. Systematic Review of Outcome Variation

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<th>Study</th>
<th>Aspect of Variation</th>
<th>Date Search Concluded</th>
<th>Date of Publication</th>
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Wilson et al. identified studies relevant to cultural variation in outcomes. The eleven studies were all observational in nature, and were relevant to advance directives, healthcare preferences, communication, and decision-making. These studies generally observed that religion and acculturation as well as ethnicity figured prominently in explaining cultural differences. African-American and Hispanic status was associated with preferences for life-sustaining treatment in several studies. Hispanic status was also associated with impaired communication secondary to language—not only about advance directives, but also pain. Several studies highlight cultural differences not only in preferences for treatment, but also in the process of decision-making with respect to disclosure and the family’s role vis-à-vis the patient’s autonomy with non-white patients more likely to prefer non-disclosure and group vs. individual decision-making.

The same review also highlighted studies related to home, nursing home, and hospital care. These reviews did not explicitly examine differences, but the individual reviews are useful by comparison. The study identified 11 studies relevant to hospital care at the end of life, 20 studies related to home death, and 22 articles related to long-term care death. With respect to hospitals, the review highlighted the fact that many patients experience a hospital death and that from the population perspective, bed supply is one of the more important determinants of site of death. Women and non-white patients were at higher risk of end-of-life hospitalization, according to several studies. Less than a third of hospitalized patients made advance care plans in several studies and high-intensity care was common, even among patients with dementia. This review highlighted the role of nursing education in palliative care—studies reported an association between education or experience in end-of-life care and management or attitudes. With respect to nursing home issues, the review highlighted descriptive studies of difficulties in pain management, personal care, communication, and caregiver support. Several studies reported an association between hospice use in the nursing home and family perceptions of better nursing home care compared to families whose loved ones did not receive hospice. With regard to home death, the review highlighted literature describing a discrepancy between preference for home death and its low rate of occurrence. Home support was associated with increased likelihood of death and care at home, although home death was also associated with emotional and practical stress on caregivers.
We identified a number of studies highlighting important healthcare system associations. Several of the highest-quality population-based observational studies that have compared the performance of systems of care have found relative deficiencies in symptom management, physician communication, emotional support, and being treated with respect in hospital and nursing home environments compared to hospice at the end of life. Observational studies of symptoms did not inform differences among settings, but did point out associations between treatment and symptoms of behavioral disturbance in dementia. Observational literature on continuity of care highlighted particular issues with continuity related to each setting of care—including hospital readmission, nursing home transfers, and multiple providers when patients are living with advanced illness.

We found little evidence to inform whether or not there are racial/ethnic differences in satisfaction, although we found evidence that racial/ethnic considerations could affect expectations regarding the quality of care, especially with regard to advance care planning and treatment preferences. A number of observational studies describe Hispanic, African-American, and other group preferences for indirect or non-disclosure, group rather than individual decision-making, and use of life-sustaining treatments. The highest-quality observational studies of pain and other symptoms also provided little information on racial/ethnic differences in pain, dyspnea, and depression and anxiety. Observational studies in caregiving and continuity similarly provided little information on racial/ethnic differences, although intervention studies of caregiving did more so (this is discussed in the summary of effectiveness of interventions). A few studies of advance care planning showed modest improvement in patient-surrogate accord with non-white race, and preferences for avoiding planning ahead for persons with poorer health or lower education. However, effect sizes were modest and studies were small and conducted in non-generalizable populations.

The observational literature was generally uninformative with regard to important differences by disease. To the extent that it does highlight differences, it is mostly a function of the fact that research on certain topics is commonly pursued in specific diseases. For example, the caregiving literature highlights problems with caregiving in dementia, although a few studies of advanced CHF also highlight the stress experienced by caregivers. For the most part, with regard to all topics, this shows our need to expand our understanding of how disease status might be associated with the kinds and chronology of needs that patients and families face.
H. Summary regarding the effectiveness of interventions

Satisfaction

Although the evidence is mixed, the preponderance of the interventional and observational literature supports the effectiveness of palliative care for improving both patient and caregiver satisfaction. Subjective measures of the end-of-life care experience include both satisfaction and quality-of-care measures, and these tools overlap significantly. Satisfaction or quality-of-care instruments that assess focused aspects of end-of-life care have been most useful in demonstrating the effects of interventions. Nonspecific satisfaction instruments or studies that use measures not specifically adapted for or developed for palliative care settings have often demonstrated ceiling effects on satisfaction. Possibly for that reason, intervention effects on satisfaction have been somewhat inconsistent.

Measures of satisfaction that are more specific and strongly related to explicit intervention aims or processes (e.g., communication, pain control, practical support, and enhanced caregiving) have demonstrated greater sensitivity to change and support a process-outcome relationship among these variables. The relationship of other processes or attributes of care (e.g., treatment of symptoms other than pain, spiritual support, continuity and coordination of care) to satisfaction is less evident in the literature although it is supported qualitatively. The ability to demonstrate relationships of these aspects of care to satisfaction may be partially related to challenges defining spiritual support as an intervention and measuring spiritual support and continuity of care.

Pain, Depression and Anxiety, and Behavioral Symptoms in Dementia

The evidence base supporting the effectiveness of interventions for cancer pain is quite strong, but better descriptive information is needed about the experience of pain at the end of life in conditions other than cancer. In cancer populations, experiments testing different opioids, different dosages of the same opioid, or different means of opioid delivery did not produce statistically significant results as highlighted in both reviews and intervention studies. These studies were among the strongest in terms of study design. Few CAM interventions had a positive impact on pain relief; acupuncture and massage produced short-term pain relief in cancer patients. Along with descriptive studies, studies of pain treatment in non-cancer conditions needs further study. None of the review studies and only four of the intervention studies included non-cancer patient samples in their studies; none of these studies were on a single disease. Studies of non-pharmacologic interventions are small and of varied quality.

Morphine and other opioids may have a beneficial impact on dyspnea; one meta-analysis and three small but promising intervention studies reported mostly positive results for cancer and COPD. No large studies have examined interventions to relieve dyspnea in cancer or non-cancer conditions, or attempted to describe the experience of dyspnea, despite the fact that dyspnea is a characteristic symptom of several important end-of-life conditions (e.g., advanced cancer, COPD, CHF). Dyspnea in advanced CHF appears to be the most understudied among these conditions. The evidence from the reviews and individual intervention studies presents relatively
negative results for the role oxygen therapy plays in the management of dyspnea in cancer patients. Exercise interventions may have a positive effect on those with severe COPD and heart failure but these have not been tested in cancer patients. In small, short-term studies, acupuncture, acupressure, and relaxation therapy showed some clinical benefits.

Effective interventions have targeted the pharmacologic treatment of depression in cancer, but relatively few studies have evaluated shorter-acting drugs, or the treatment of depression in non-cancer conditions. We reported on one extensive review of the intervention literature regarding depression in cancer patients. Of the seven interventions considered, five focused on the treatment of depression and/or anxiety in cancer patients as well. The other review and two intervention studies focused on other disease cohorts (one study focused specifically on depression in heart failure patients, the other on mixed disease). SSRIs have been shown to be very successful in treating depression in palliative care populations. Behavioral and CAM interventions have demonstrated mixed results.

The existing literature on dementia has focused primarily on Alzheimer’s disease. Given the considerable amount of time one can live after a diagnosis of dementia, these studies are somewhat limited in the context of this review because it is not clear how many of them include a population clearly near the end of life. The literature addresses many symptoms for the dementia patient population: aggressive/disruptive behavior, agitation, wandering, and mood were the most common. These studies suggest that a variety of non-pharmacologic therapies may be effective for behavioral symptoms in dementia. Pharmaceutical interventions were the subject of only a few studies and with mixed results. There are many more methodological limitations in the literature on dementia making it difficult to make definitive statements about the best treatment for these patients.

**Caregiving Burden**

In general, a variety of interventions were studied for a broad range of caregivers (e.g., spouse, adult children, others), primarily caregivers to dementia patients and to terminal cancer patient caregivers, usually as a supplement to clinical palliative care services being provided to the terminally ill patient. Most studies, whether on dementia or end-of-life caregiver interventions, focused on caregiver burden (objective and subjective burden) as the main outcome measure, but outcomes also included psychological distress (stress, depression), anxiety, coping skills, life satisfaction, health related quality of life, satisfaction with services or care, morale, rate of home death, rates of institutionalization, and costs.

There were generally two kinds of interventions used to address caregiver burden: individual and group interventions. The interventions included education, counseling, support groups, home health, hospice, or palliative care services to caregivers singly, or in some combination. For the most part, intervention studies have reported inconsistent results. Larger treatment effects have been found for individual interventions, yet group interventions predominate the literature (Knight, Lutzky, & Macofsky-Urban, 1993). In addition, only multi-component interventions and some respite services have shown positive (though small) impacts on caregiver burden. The inconsistencies in the literature may be attributable to the differences in the caregiver outcome measurement, research design, and analytical methods used.

The caregiving interventional literature provides some information about ethnic or racial differences in caregiving experience. Caregiver race was significantly associated with the effect size of some interventions. Several studies in our review demonstrated such differences with
regard to African-American and White caregivers. Race was significantly associated with
caregiver intervention impact \( (p<.001) \), indicating that the treatment was more effective for non-
white caregivers.\(^{257}\) Hispanic men and Hispanic and White daughters experienced a higher
impact from Birmingham REACH intervention than other groups.\(^ {264}\)

Overall, palliative care teams do appear to have a small but beneficial effect on patient
outcomes. In contrast, small effects have been found related to caregiver outcomes. There is also
no significant effect of palliative care teams on home death rates, no matter what the make-up of
the team.\(^ {72, 74}\)

**Continuity**

The preponderance of systematic reviews and interventions supports the efficacy of
interventions to improve continuity in the context of palliation of cancer. In addition, we found
some lower-quality evidence that palliative HIV care could improve continuity. Interventions
embody a variety of successful approaches including aspects of management, informational, and
interpersonal continuity as well as comprehensive integrated care such as palliative care services.
We found evidence for the effectiveness of interventions targeting care at multiple levels—
provider, patient, provider/patient interface, and multiple settings but particularly home and
hospital. Our review is limited in that it identified no evidence related to improving continuity
across multiple sites of care.

Although we identified many effective interventions for improving continuity in CHF care,
few of these explicitly addressed or reported patient-centered palliative outcomes (e.g., dyspnea,
advance care planning, caregiving impact). However, successful interventions share features of
successful interventions in general including longer intervention periods, coordination among
providers, and regular, structured home assessment. Many CHF interventions specifically
excluded patients who were ‘terminally ill,’ limiting their generalizability. We identified no
palliative interventions targeting other conditions and continuity of care—other than in the
context of unselected populations that were more commonly focused on cancer care. Most
interventions have targeted re-admission to the hospital or other kinds of high-cost care, but
interventions are needed to understand how to improve other aspects of continuity as well.

**Advance Care Planning**

The usual practice of advance directives and advance care planning is supported by little
reliable scientific evidence of efficacy in improving outcomes. Improved communication and
planning has some tendency toward improved patient and family satisfaction, and certainly
anecdotes and small series point to patient and family frustration and disappointment with
seriously flawed communication. Nevertheless, high-quality research designs have not often
been applied to these questions and, when applied, have shown quite modest effects, even on
increasing the rate of making decisions in advance. Whether improved advance care planning
actually improves the experience for patients and their families has only thin and equivocal
evidence.

However, studies provided several key insights involving advance care planning. First,
advance care planning has to reflect changing preferences and circumstances; patients’
preferences change over the course of their illness. Second, when clinicians and families
understand and agree with patients’ preferences and prognosis, patients are more likely to
experience preferred outcomes. Third, physical and psychosocial support for patients and their
families is needed and can improve communication and decision-making among clinicians, patients, and families. Fourth, interventions limited to one type of strategy and one site of care, as well as those that have few study subjects, are not likely to change care patterns or have long term impact. For about half of the studies reviewed here, only one site of care was used and a small number of patients were enroll.