



Comparative Effectiveness of Home-based Kidney Dialysis versus In-center or Other Outpatient Kidney Dialysis Locations – A Systematic Review

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PREFACE

Quality Enhancement Research Initiative's (QUERI) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) clinicians, managers and policymakers as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout the VA, and some evidence syntheses inform the clinical guidelines of large professional organizations.

QUERI provides funding for four ESP Centers and each Center has an active university affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence;
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of HSR&D Central Office and the four ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of QUERI field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at Nicole.Floyd@va.gov.

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ABBREVIATIONS TABLE

APD	Automated peritoneal dialysis
CAPD	Continuous ambulatory peritoneal dialysis
CCPD	Continuous cycling peritoneal dialysis
CCT	Controlled, clinical trial
CKD	Chronic kidney disease
eGFR	Estimated glomerular filtration rate
ESRD	End-stage renal disease
HD	Hemodialysis (in-center)
HHD	In-home hemodialysis
PD	Peritoneal dialysis
RCT	Randomized, controlled trial
RRT	Renal replacement therapy
VA	Veterans Affairs

EVIDENCE REPORT

INTRODUCTION

Home-based dialysis (defined for this review as in-home hemodialysis [HHD] or peritoneal dialysis [PD]) may offer advantages over in-center hemodialysis (HD) including patient convenience, expanded capacity for VA to deliver fully integrated care to Veterans with end-stage renal disease (ESRD), a reduction in fee-basis costs associated with dialysis, and potentially improved patient quality of life and blood pressure control with greater survival and fewer hospitalizations. Home-based dialysis may also increase ability to care for patients living distant from existing medical centers.¹ Home-based dialysis may also allow for more frequent or longer dialysis sessions than conventional (3 times per week for 3 to 4 hours) hemodialysis.² Disadvantages include the need for a relative or friend to assist (especially with HHD) and the strain that may put on relationships.²

In the United States Renal Data System (USRDS) 2014 Annual Report, it was reported that on December 31, 2012, 402,514 patients (65%) with ESRD were receiving HD, 40,605 (7%) were being treated with PD, and 175,978 (28%) had a functioning graft.³ Renal replacement therapy was received at home by 49,000 patients with 16% receiving HHD and 84% receiving PD. It was noted that 5 times more patients were using HHD in 2012 (N=7,923) than in 2002 (N=1,563).

A 2003 systematic review included RCTs (k=1; reporting only on blood pressure control), comparative observational studies (k=22), or systematic reviews (k=4) of HHD versus in-center HD (hospital-based or satellite unit) published through 2001.² Fourteen studies were conducted in the US. HHD was limited to home hemodialysis using similar equipment and consumables as in-center HD. Sixteen studies (3 systematic reviews and 13 comparative observational studies) reported on quality of life. Although different measures of quality of life were reported, the overall finding was higher quality of life in HHD patients. Of 4 studies that assessed social aspects related to quality of life, 3 found HHD more disruptive for families or that the spouse was less satisfied with the location of the HD compared to in-center HD. The 2003 review also included mortality data from 9 studies – a systematic review published in 1995 and 8 comparative observational studies published from 1978 to 1999. In the 7 studies comparing HHD with in-center HD, survival was generally greater in the HHD groups although some differences were noted depending on the length of follow-up or age at start of RRT. Results were mixed for the 2 studies comparing HHD to HD in free-standing dialysis units; one study reported no difference in survival and the other reported greater survival in the HHD group. The authors noted that HHD patients typically had fewer comorbidities than in-center HD patients. Only one study reported technique survival (the time a person remains on a particular form of RRT) with longer median technique survival in-center HD patients compared to HHD patients.

As the number of Veterans requiring RRT increases, there is a need to expand the Veteran Administration's ability to provide these services by either outsourcing them to the community, expanding in-center dialysis program, or increasing home dialysis (PD or HHD) modalities use among Veterans with ESRD. In order to inform the ESRD program development, the VA commissioned an up-to-date review of the benefits and harms of home-based HD (HHD and PD) versus in-center HD, the benefits and harms of different home-based dialysis modalities, and the predictors of successful home-based dialysis. We focused our review on studies of adults with

chronic kidney disease requiring dialysis and comparing home-based and in-center HD. Due to differences in healthcare systems, we further limited the review to studies from North America, Europe, or Australia/New Zealand. We address the following key questions developed with input from topic nominators and a technical expert panel (TEP):

Key Question 1. What are the benefits and harms (*ie*, all-cause mortality, cardiovascular events, hospitalizations, depression, cognitive impairment, quality of life, conversion to a different type of dialysis, complications related to vascular access, complications of dialysis) of *in-home* compared to *in-center hemodialysis*?

1a. What are the benefits and harms (*ie*, all-cause mortality, cardiovascular events, hospitalizations, depression, cognitive impairment, quality of life, conversion to a different type of dialysis, complications related to vascular access, complications of dialysis) of the various modalities of in-home hemodialysis (*ie*, short daily, nocturnal) compared to conventional hemodialysis?

Key Question 2. What are the benefits and harms (*ie*, all-cause mortality, cardiovascular events, hospitalizations, depression, cognitive impairment, quality of life, conversion to a different type of dialysis, complications related to vascular access, complications of dialysis) of *peritoneal dialysis* compared to *in-home hemodialysis* or *in-center hemodialysis*?

2a. Do results differ depending on whether peritoneal dialysis was the initial therapy or the therapy used following failed in-center dialysis?

Key Question 3. What are the a) health care system, b) provider, and c) patient factors associated with selection of and technique survival for home-based dialysis (including peritoneal dialysis)?

Key Question 4. In the published literature, what are the costs of home hemodialysis or peritoneal dialysis compared to in-center hemodialysis?

METHODS

TOPIC DEVELOPMENT

This topic was nominated by Susan Crowley, MD, VHA National Program Director for Kidney Disease and Dialysis and Rudolph Rodriguez, MD, Chair, VA Renal Field Advisory Committee. Key questions and outcomes were developed with input from a Technical Expert Panel.

SEARCH STRATEGY

MEDLINE and the Cochrane Library were searched from 1995 to December 2013 for randomized controlled trials (RCTs), controlled clinical trials (CCTs), and observational studies. The search strategy included MeSH terms and keywords for HD and peritoneal dialysis (Appendix A).

STUDY SELECTION

We included studies of adults with chronic kidney disease receiving dialysis (in-center HD, HHD, or PD) as outpatients. We excluded studies that did not report our outcomes of interest.

Primary Outcomes:

KQ1, KQ2 – All-cause mortality

KQ3 – Health system organizational factors, provider knowledge, patient factors (age, race, gender, caregiver support, social support, comorbidities, cognitive function, physical abilities, rural vs urban [distance from dialysis center], home vs assisted living or skilled care facility)

KQ4 – Costs (from literature)

Secondary Outcomes:

KQ1, KQ2 – Cardiovascular events (MI, stroke, cardiovascular death); hospitalizations; clinically diagnosed depression or cognitive impairment; clinically meaningful difference in quality of life scale scores; conversion to a different type of dialysis (*eg*, from peritoneal to in-center hemodialysis)

Intermediate Outcomes:

KQ1, KQ2 – Quality of life (EuroQoLEQ, Kidney Disease QOL) scale scores; depressive symptoms; cognitive function; total and mental- and physical-health subscale scores

Harms:

KQ1, KQ2 – Complications related to vascular access including button hole technique (access failure, infection requiring procedure, thrombectomy, angioplasty, fibrin striping of catheters, replacement of catheters); complications of dialysis (fluid and electrolyte disorders requiring hospitalization, additional dialysis, or both, symptomatic hypotension)

We included all RCTs or CCTs that met eligibility criteria. For Key Questions 1 and 2, we required registry studies to enroll at least 1,000 patients and have a mean or median follow-up of

at least one year if they reported outcomes of mortality, cardiovascular events, technique failure, or transplantation. For all other outcomes and for Key Question 3, a minimum enrollment of 100 and a mean or median follow-up of at least one year was required. Additionally, for Key Question 3, we included studies of dialysis modality selection only if they followed patients to determine the dialysis modality the patient received.

DATA ABSTRACTION

From registry studies we extracted study characteristics (dialysis modalities, study purpose, cohort years, country, sample size, and patient inclusion criteria), patient characteristics (age, gender, and race), data analysis technique (factors adjusted for, modeling technique, analysis approach), length of follow-up, and outcomes. If reported, we also extracted data on interactions between mortality and age, gender, race, body mass index (BMI), diabetes, cardiovascular disease, and duration of ESRD therapy.

For mortality outcomes, most of the registry studies presented more than one analysis approach (different statistical model, different adjustment factors, *etc*). We extracted the most-adjusted model. Many studies reported outcomes at multiple time points during the follow-up period. We focused on data at one year, 2 years, and at maximum follow-up time, if provided.

QUALITY ASSESSMENT

For included RCTs and CCTs, trained research methodologists rated the risk of bias of individual studies as low, moderate, or high risk. Risk of bias ratings were based the following criteria: allocation sequence generation, allocation concealment, blinding, incomplete outcome data, and selective outcome reporting – a modification of the Cochrane approach to determining risk of bias.⁴

For observational studies, trained methodologists assessed risk of bias using criteria suggested in the AHRQ Methods Guide: selection bias (use of appropriately comparable control group, design/analysis accounted for important confounding and modifying variables); masking of the outcome assessment (outcome assessor); use of intention-to-treat principles (*ie*, inclusion of all comparison group participants in outcomes analyses); attrition bias (if overall or differential dropout/loss to follow-up or exclusions a concern, missing data appropriately handled); and selective reporting of prespecified outcomes.⁵ Observational studies were considered high risk of bias unless all 5 criteria were addressed by the study authors. Studies that addressed all 5 criteria were considered moderate or low risk of bias depending on how completely the criteria were addressed.

Quality of existing systematic reviews was assessed using the Assessment of Multiple Systematic Reviews (AMSTAR) criteria.⁶

DATA SYNTHESIS

Due to differences in study methodology, data could not be pooled. For Key Questions 1 and 2, we summarize the results by outcome. For Key Question 3, we summarize findings for health care system, provider, and patient factors. For Key Question 4, we summarize costs of HHD versus in-center HD and PD versus in-center HD.

RATING THE BODY OF EVIDENCE

We rated strength of evidence for our main outcome (mortality) as reported in the registry studies for the comparisons of HHD to HD and PD to HD. The rating is based on risk of bias of individual studies and consistency, precision, and directness of the overall evidence as described by Owens et al.⁷

PEER REVIEW

A draft version of this report was reviewed by clinical content experts as well as clinical leadership. Their comments and our responses are presented in Appendix B and the report was modified as needed.

RESULTS

The majority of studies identified compared in-center hemodialysis (HD) to peritoneal dialysis (PD). Relatively few studies compared in-home hemodialysis (HHD) to HD or PD.

LITERATURE FLOW

Details of the literature search and study selection process are presented in Figure 1. For Key Questions 1 and 2, we identified 32 registry studies (16 from the US, 4 from Canada, 3 from Australia/New Zealand, 7 from Europe or the UK, and 2 multi-national) that compared PD to HD. Seven registry studies (4 from the US, 2 from Australia/New Zealand, one from the UK, and one multinational study) provided data for the comparison of HHD to HD. Two registry studies (one from the US and one from the UK) also compared HHD to PD.

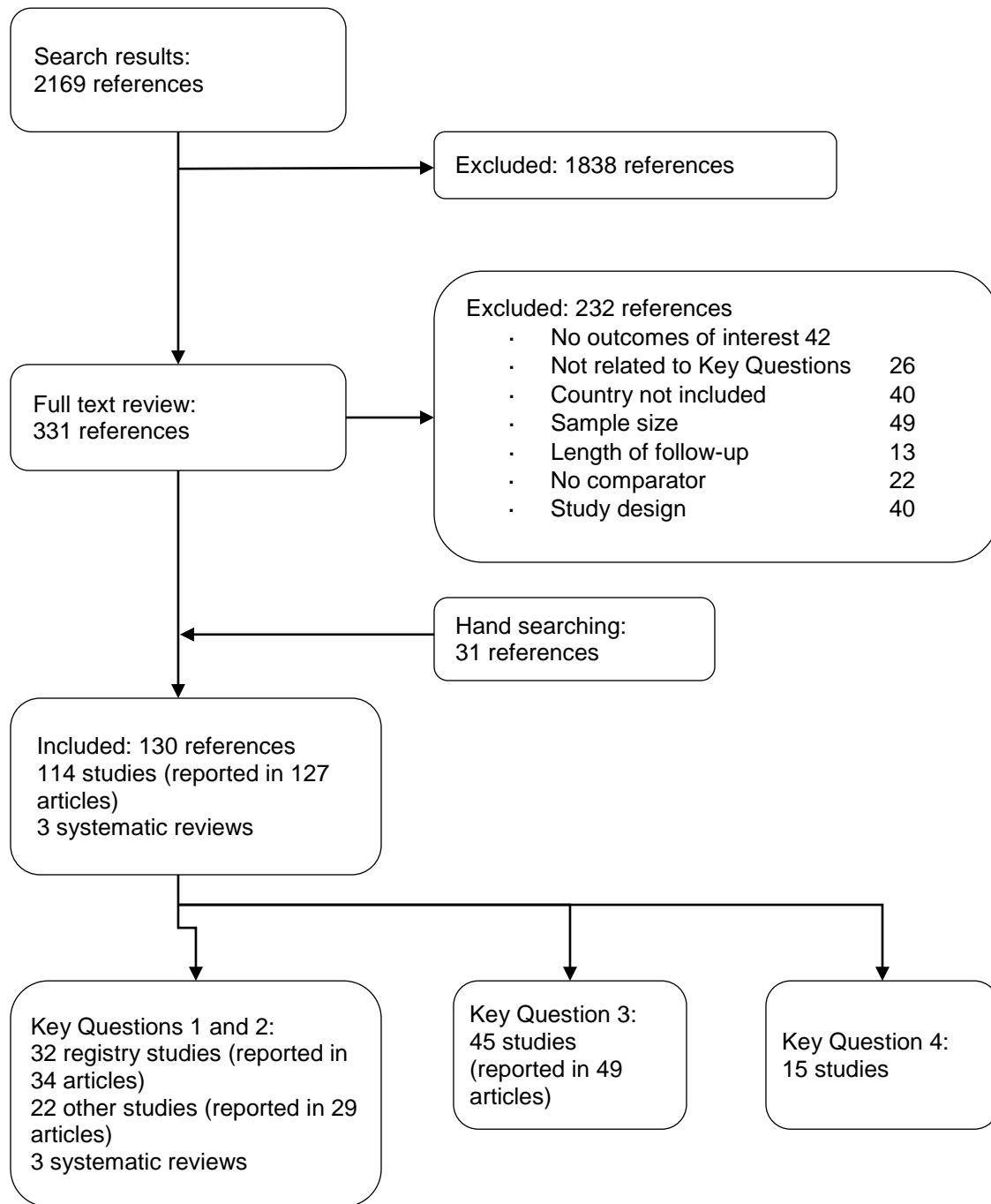
We also identified 3 RCTS. One study from Canada and one from New Zealand compared HHD to HD; one study from the Netherlands compared PD to HD. We identified 3 CCTs (one from the US, one from Canada and one multinational study) that compared HHD to HD and 2 clinical cohort studies (one from the US and one from the Netherlands) that compared PD to HD.

To further address other Key Question 1 and 2 outcomes (hospitalization, quality of life, cognitive, depression, and adverse events) we report findings from systematic reviews, RCTS, CCTs, longitudinal studies, and cross-sectional studies. There were 15 articles from Europe or the UK, 5 from the US, 4 from Canada, and one from Australia/New Zealand; the systematic reviews were multinational.

For Key Question 3, we included 49 articles, 16 from the US, 17 from Canada, one from the US and Canada, 12 from Europe/UK, 2 from Australia/New Zealand, and one multinational. Most of the studies addressed either patient factors associated with selection of a dialysis modality or factors associated with technique survival for PD.

We identified 15 studies that reported cost outcomes (Key Question 4) comparing either PD to HD or HHD to HD. There were 2 studies from the US, 6 from Canada, 6 from Europe/UK, and one from Australia/New Zealand.

Figure 1. Literature Flow Chart



KEY QUESTION 1. What are the benefits and harms (*ie*, all-cause mortality, cardiovascular events, hospitalizations, depression, cognitive impairment, quality of life, conversion to a different type of dialysis, complications related to vascular access, complications of dialysis) of *in-home compared to in-center hemodialysis*?

Summary of Findings

- Evidence is generally of high risk of bias regarding the comparative effectiveness of HHD versus in-center HD. We found few randomized or controlled clinical trials or prospective clinical cohort studies comparing in HHD and in-center HD. Available clinical trials were small in size, had short follow-up durations, and focused on intermediate outcomes rather than mortality outcomes.
- Strength of evidence for mortality was low based on high risk of bias associated with the registry studies. Results from registry studies should be interpreted with caution due to likely residual confounding.
- Of 7 registry studies included, 5 suggest that HHD is associated with improved overall survival compared to in-center HD. One registry study found a benefit for individuals receiving in-center HD over HHD while another found no difference. Two small RCTs of short follow-up duration reported no difference in mortality between in-center versus in-home modalities. A multinational CCT with 415 patients and 1006 patient-years of follow-up reported a mortality benefit for HHD compared to in-center HD while a small, short-duration CCT found no difference.
- Two registry studies reported no difference in cardiovascular mortality.
- Limited data suggest that HHD patients may be more likely than in-center HD patients to switch dialysis modalities at some point during their treatment but no differences in rate of transplant or all-cause hospitalizations were observed. Results for quality of life and adverse events were mixed with some studies showing benefits of HHD and others showing no difference.
- No studies suggested HHD was associated with harms.

In-Home Hemodialysis (HHD) Compared to In-Center Hemodialysis (HD)

Study Characteristics

Seven registry studies,⁸⁻¹⁴ 2 RCTs,^{15,16} and 3 CCTs¹⁷⁻¹⁹ reported mortality data for HHD and in-center HD programs. Another registry study reported hospitalization data.²⁰ Among the registry studies, 4 were from the US Renal Data System (USRDS),^{8-10,20} two were from the Australia and New Zealand Dialysis and Transplant (ANZDATA) Registry,^{11,12} one was from the UK (England and Wales),¹⁴ and one was completed in 3 countries – the US, Canada, and France, with the majority of patients from Canada.¹³ Across the studies, registry enrollment occurred between 1986 and 2011; follow-up periods were up to 15 years. Sample sizes ranged from 1,726¹³ to 458,329⁹ with all but one study¹³ enrolling only incident HHD patients. Three studies

included matched prevalent HD patients.^{8,13,20} HHD patients tended to be younger.⁹⁻¹³ Three studies reported a higher percentage of males in the HHD group,¹¹⁻¹³ one reported the HHD patients were more likely non-white,⁹ and 2 reported the HHD patients were more likely white or other race.^{12,14} Additional information about patients included in the registries is presented in Appendix C, Table 1.

Methods used for data analysis were similar in 4 of the studies – a Cox proportional hazards model and an intent-to-treat analysis with adjustment for patient demographics, and, in most studies, comorbid conditions and laboratory variables.^{8-10,13} One used a Cox proportional hazards model with an “as-treated” approach¹¹ while another study used a marginal structural modeling (MSM) technique with an “as-treated” analysis.¹² Appendix C, Table 1 provides further details on the analysis approach used in each study.

We also included data from 2 RCTs, one from Canada¹⁵ and one from New Zealand¹⁶ (Appendix C, Table 2). The study from Canada randomized patients to either 3 dialysis sessions per week (52% of the patients received in-center HD) or 5 to 6 dialysis sessions per week at home. The total sample size was 61 patients and follow-up was 6 months.¹⁵ The study from New Zealand was a cross-over RCT with 9 patients and 8 weeks per intervention period.¹⁶ The interventions were in-center HD for 3.5 to 4.5 hours per day, 3 times per week and HHD for 6 to 8 hours, 3 times per week.

One CCT was a multinational study (US, Italy, France, and the UK),¹⁸ one was from the US,¹⁷ and one was from Canada.^{19,21} The multi-national study enrolled 415 patients and both HD and HHD followed short, daily protocols. A total of 1,006 patient years of follow-up was reported.¹⁸ The US study enrolled 63 nocturnal (5 to 6 times per week) HHD patients and 121 matched conventional (3 times per week) HD patients. Patients were followed for up to 20 months.¹⁷ The study from Canada included a conventional in-center HD group (3.5 to 4.5 hours, 3 times per week), a nocturnal HHD group (6 to 8 hours, 5 to 6 times per week), and a daily HHD group (1.5 to 2.5 hours, 5 to 6 times per week).¹⁹ Follow-up was 18 months. Additional study data are reported in Appendix C, Table 2.

Mortality

A summary of mortality outcomes is presented in Table 1. Five of 7 registry studies reported lower mortality overall in HHD patients with hazard ratios ranging from 0.48 to 0.88.^{8,10-13} In 2 studies, the benefit was also observed at follow-up intervals of one, 2, or more than 3 years.^{11,12} One study reporting a benefit included only NxStage System One users.⁸ The HHD group in this study completed 5 to 6 dialysis sessions per week. Although there was an overall benefit of HHD, the benefit was not observed at the 2 year follow-up assessment.⁸ In another study, the HHD was “intensive” – sessions of at least 5.5 hours, 3 to 7 times per week.¹³ One study reported a higher mortality in the HHD group (HR 1.10 [95% CI 1.04, 1.17])⁹ and one study reported no difference (HR 1.06 [95% CI 0.55, 2.04]).¹⁴ Data are presented in Appendix C, Table 1.

The 2 RCTs and 2 of the CCTs reported no difference in mortality between HD and HH (Appendix C, Table 2).^{15-17,19} The other CCT reported higher mortality in the HD group (HR 2.42 [95% CI 1.54, 2.79]).¹⁸ Findings from the RCTs and CCTs should be interpreted with caution given the small sample sizes and short follow-up periods.

Three of the registry studies looked at the interaction of age and modality on mortality outcomes (Table 1 and Appendix C, Table 3). A study from Australia/New Zealand reported a significant interaction by age at dialysis inception ($P = .03$). The decrease in mortality risk associated with HHD was less for patients in the older age group (greater than 74 years).¹² A more recent report from this group reported that the effect of modality on mortality risk was not modified within subcategories of age.¹¹ The multinational study also reported no significant interaction with age.¹³

One Australia/New Zealand study reported a significant interaction by ethnicity ($P < .001$) finding that the decrease in relative mortality risk associated with HHD was less for non-whites and non-Asians.¹² The authors also reported no difference in risk between patients with and without diabetes. The more recent report found no differences in risk based on ethnicity, BMI, presence of cardiovascular disease, or duration of ESRD therapy.¹¹ The multi-national study reported non-significant interactions between mortality and duration of ESRD.¹³

Other Outcomes

Cardiovascular Events (Appendix C, Table 1)

One US registry study reported cardiovascular mortality.⁸ The overall (maximum follow-up of 4 years) cardiovascular mortality did not differ between HHD and HD (HR 0.92 [95% CI 0.78, 1.09]). From an Australia/New Zealand registry study, the percentages of cardiovascular deaths by dialysis modality were 65% for HHD and 47% for HD.¹² Follow-up in this study was a maximum of 11 years and 9 months.

Hospitalization (Appendix C, Table 4)

One registry study reported hospitalizations.²⁰ There were no significant differences between HHD and matched HD patient groups for all-cause hospitalization or hospitalization for vascular access dysfunction. There was a significantly greater risk of hospitalization for infection (RR 1.32 [95% CI 1.24, 1.40]) and decreased hospitalization for cardiovascular causes (RR 0.83 [95% CI 0.78, 0.88]) in the HHD group. One of the RCTs reported no difference in all-cause hospitalization with rates of 0.62 (HHD) and 0.84 (HD) per patient over the 6 month follow-up period.¹⁵ A CCT, also from Canada, found no difference in hospitalization between conventional HD and either nocturnal HHD or daily HHD patients.¹⁹

Table 1. Mortality – In-center Hemodialysis (HD) vs Home Hemodialysis Dialysis (HHD) – Registry and Trial Data

Country/ Region: Number of Reports	Study Years	Patients: Number of Reports or Sample Size	Overall Mortality: Number of Reports			Number of Studies Reporting Effects by:						
			No difference	Favor HHD	Favor HD	Age	Gender	Race	BMI	DM	CVD	ESRD Duration
REGISTRY STUDIES												
USA: 3	1986-2008	Incident: 3 (1 with matched prevalent HD)		2 ^a	1							
Australia/ New Zealand: 2	1996-2011	Incident		2 ^b		2		2	1	1	1	1
UK: 1	1997-2005	Incident	1									
International : 1	2000-2010	Incident and prevalent HHD, matched HD		1 ^c		1						1
RANDOMIZED CONTROLLED TRIALS												
Canada: 1	2004-2006	N=61	1									
New Zealand: 1	NR	N=9 (cross- over RCT)	1									
CONTROLLED CLINICAL TRIALS												
USA: 1	1997-2010	N=184	1									
International : 1	1982-2005	N=415		1								
Canada: 1	1998-2001	N=46	1									

^a One study reported no difference after 2 or more years

^b Overall, at 1 year, 2 years, and >3 years

^c HHD was intensive (>5.5 hours per session, 3-7 sessions per week)

Quality of Life, Cognition, Depression (Appendix C, Table 4)

Quality of life, cognition, and depression outcomes were not reported in the registry studies. In the Canadian RCT, no difference was noted between HHD and HD patients in change in EuroQol-5D scores over 6 months.¹⁵ There were significantly greater improvements in two elements of the KDQOL instrument, Effects of Kidney Disease (difference (HHD-HD) in change over 6 months: 8.6; P = .01) and Burden of Kidney Disease (difference (HHD-HD) in change over 6 months: 9.4; P = .02) in the HHD group compared to the HD group. The cross-over RCT from New Zealand also reported quality of life, finding that HHD interfered more with social activities (P < .05), tended to be to be more of a burden on families (P = .07), and was associated with less physical suffering (P < .005).¹⁶ The CCT from Canada found no difference between HHD and either daily or nocturnal HD in the SF-36 physical or mental component scores at 18 months.²¹

A cross-sectional study from the UK included 145 patients receiving HD, HHD, or PD.²² The study found a significant difference across modalities in scores on the Treatment Effects Questionnaire but subsequent analyses found that the difference was only between modalities of



PD. Using a Beck Depression Inventory cut-off score of 16 or higher as an indication of depression, 42% of the HD group was classified as having depression compared to 8% of the HHD group but the difference was not statistically significant. Similarly, with a cut-off score of 10 or higher on the Cognitive Depression Index, 31% of the HD and 12% of the HHD group were classified as having depression but the difference was not statistically significant. It was noted that the duration of treatment was significantly longer in the HHD group (88 months) than the HD group (39 months).

An earlier study from the UK with 192 patients receiving HD, HHD, or PD reported scores on components of the SF-36.²³ There were significant differences across modalities (with HHD patients having higher scores) for Physical Functioning (HD 28, HHD 47), Role Physical (HD 17, HHD 41), Social Functioning (HD 49, HHD 63), and Role Emotional (HD 30, HHD 65). The study reported the percentage of patients receiving treatment for 9 months or less: 85% of the HD group and 62% of the HHD group.

A Canadian study enrolled 119 patients receiving HD, HHD, or PD.²⁴ The duration of treatment was 44 months for the HD group and 38 months for the HHD group. No significant difference was noted between HD and HHD patients on the Self-Anchoring Striving Scale. On the Index of Well-Being and the Health State Utility/Time Trade-off, scores for HHD patients were significantly higher than HD patients.

Change in Dialysis Modality (Appendix C, Table 1)

One US registry study reported a significantly greater risk of changing dialysis modalities in the HHD patients compared to the HD patients (HR 10.4 [95% CI 8.9, 12.3]).⁸ Over the follow-up of up to 4 years, 26% of the HHD patients changed modality (97% to HD, 3% to PD) compared to 3% of the HD patients. The multi-national study reported that over a maximum follow-up of 4 years (median of 1.8 years), 14% of the HHD patients switched modalities (all to HD) compared to 0% of the HD patients.¹³ The study from the UK reported that median technique survival for HHD was 18 months (IQR 9 to 33 months).¹⁴ Of 130 patients with known reasons for stopping HHD, 30 (23%) switched to HD (hospital or satellite) and 1 (0.8%) to PD. The remaining patients either underwent kidney transplant (n=77) or died (n=22). The recent CCT from the US reported no significant difference in percentage of either HHD or HD patients who transferred to PD.¹⁷

Transplantation (Appendix C, Table 1)

A US registry study found no difference in the percentage of patients receiving a transplant (HHD 10.2%, HD 10.8%, HR 1.05 [95% CI 0.89, 1.25]).⁸ The multinational study also reported no difference in transplantation between HHD and HD (9.5 and 8.8/100 person-years, respectively).¹³ The maximum follow-up was 4 years in both studies; the multinational study reported a median follow-up of 1.8 years.

Adverse Events (Appendix C, Table 4)

The Canadian RCT, a 6 month study, found no difference in adverse events between HHD and HD.¹⁵ Specifically, there were no significant differences in the number of patients with one or more cases of infection requiring a procedure or the number of patients with one or more vascular access surgical interventions. For adverse event reporting, the Canadian CCT combined

data from the daily and nocturnal HHD groups.¹⁹ The annual rates of access complications and access interventions did not differ between the HHD groups and the HD group.

Another CCT, from Italy, including 148 patients on either conventional HD (mostly in-center) or daily HD (70% at home), reported a significant difference in the rate of access closures (9.8 per 100 patient-years in the HD group, 2.2 per 100 patient-years in the HHD group; rate difference 7.6 [95% CI 3.4, 11.9], $P < .01$).²⁵ There was also a significant difference in the 3-year probability of access survival (70% HD, 92% HHD; $P < .05$).

Catheter-related events were reported in the recent CCT from the US.¹⁷ Considering only the first catheter, there was no difference between groups in the rate of sepsis (16% HHD, 12% HD; $P = .21$) or time to sepsis ($P = .98$). Median catheter duration was 5.6 months in the HHD group and 4.6 months in the HD group ($P = .64$).

KEY QUESTION 1A. What are the benefits and harms (ie, all-cause mortality, cardiovascular events, hospitalizations, depression, cognitive impairment, quality of life, conversion to a different type of dialysis, complications related to vascular access, complications of dialysis) of the various modalities of in-home hemodialysis (ie, short daily, nocturnal) compared to conventional hemodialysis?

Different In-Home Modalities Compared to In-Center Hemodialysis

Few studies included different HHD modalities. The registry study from Australia/New Zealand included patients receiving more frequent or extended (including nocturnal and short daily regimens) HD and HHD.¹² Over a follow-up period of up to 11 years and 9 months, there was reduced mortality with more frequent or extended HHD compared to HD (HR 0.53 [95% CI 0.41, 0.68]), a finding similar to the reduction in mortality with any HHD compared to HD. The percentages of deaths due to cardiovascular causes were 65% for the HHD group and 73% for the more frequent or extended HHD group.¹² As noted above, in 3 other registry studies the HHD was longer and/or more frequent than the conventional HD. Two reported reduced mortality overall (maximum follow-up of 4 years) in the HHD group.^{8,13} In one study reporting cardiovascular mortality, there was no difference between HHD and HD.⁸ A more recent study reported no difference in all-cause hospitalizations although, as noted above, there were differences between groups for different causes of hospitalization.²⁰

In 4 of the RCTs and CCTs cited above, the HHD regimens were different in frequency and/or duration than the HD regimens.^{15-17,19} None of the studies reported a mortality difference between HHD and HD. Additionally, the recent CCT reported no differences between more frequent and extended HHD and conventional HD in catheter-related sepsis, median catheter life, or transfer to PD.¹⁷ Another CCT reported no difference in hospitalizations.¹⁹ Follow-up periods ranged from 8 weeks¹⁶ to 20 months.¹⁷

Risk of Bias for Key Question 1

We did not assess the risk of bias of individual registry studies. Registry studies are typically considered high risk of bias due to issues with selection bias and inability to assess and include all potential confounders in analyses. There were 2 RCTs that addressed Key Question 1, one

moderate risk of bias and one high risk of bias. The 3 CCTs were rated as moderate (k=1) and high (k=2) risk of bias. Three cross-sectional studies were all rated as high risk of bias. Additional information is presented in Appendix C, Table 2.

KEY QUESTION 2. What are the benefits and harms (*ie*, all-cause mortality, cardiovascular events, hospitalizations, depression, cognitive impairment, quality of life, conversion to a different type of dialysis, complications related to vascular access, complications of dialysis) of *peritoneal dialysis compared to in-home hemodialysis or in-center hemodialysis*?

Summary of Findings

- Evidence is inconsistent whether mortality differs between patients treated with PD compared to in-center HD.
- Strength of evidence for mortality was low based on high risk of bias associated with the registry studies. Results from registry studies should be interpreted with caution due to likely residual confounding.
- Twenty-seven registry studies, one RCT, and 2 clinical cohort studies provided evidence for the comparison of PD to in-center HD. Of 22 registry studies reporting mortality for the total sample, 12 (2 from the US, 3 from Canada, 1 from Australia/New Zealand, and 6 from Europe/UK) found no difference in mortality between PD and in-center HD. Four studies (2 from the US, one from Canada, and one from Europe/UK) found a mortality benefit for PD while 6 studies (3 from the US, 2 from Australia/New Zealand, and one from Europe/UK) found a mortality benefit for in-center HD. It is difficult to assess if results vary by time of publication due to differences in study populations, length of follow-up reported, and methods of data analysis, but publication dates suggest that a trend may exist. Studies showing increased mortality with PD compared to in-center HD were generally published before 2003 while studies showing no difference or reduced mortality with PD were generally published after 2003.
- A small RCT from the Netherlands found no difference in mortality between PD and in-center HD. This study was terminated due to low enrollment. A prospective, clinical cohort study from the United States with 1,041 patients and a follow-up of up to 7 years found no difference in mortality. Data from a prospective cohort study from the Netherlands showed no difference in 2-year mortality.
- Analyses of interactions between dialysis modality and age (10 studies), gender (4 studies), race (5 studies), BMI (5 studies), diabetes (12 studies), cardiovascular disease (6 studies), and duration of ESRD (3 studies) yielded mixed results.
- Of 5 registry studies reporting cardiovascular disease risk, one reported a significantly higher percentage of deaths due to cardiovascular disease in the PD group. In 3 of 5 studies reporting, hospitalizations were higher in the HD groups. Mixed results were reported for quality of life outcomes including mental and physical health components, quality of life utilities, and life participation activities. Changes in treatment modality and kidney transplantation were generally more likely for patients receiving PD.
- Few studies reported adverse events.

- There is limited evidence for the comparison of PD and HHD. In 2 registry studies, results were mixed with a study from the United States finding no difference in mortality and a study from the United Kingdom finding a mortality benefit for HHD. Other outcomes were not reported.
- Two studies reported higher mortality among patients who initiated ESRD treatment with HD and then switched to PD compared to patients who initiated PD as their first modality. Overall duration of ESRD was likely longer in the patients who initiated with HD.

Peritoneal Dialysis (PD) Compared to In-Center Hemodialysis (HD)

Study Characteristics

Twenty-seven registry studies reported mortality outcomes for patients receiving HD or PD. There were 11 reports of Centers for Medicare and Medicaid (CMS) data²⁶⁻³⁶ representing patient data from 1987 to 2006. Maximum follow-up ranged from one to 6 years. Sample sizes ranged from 3,337 to 684,426 and all but one³⁵ reported data from incident patients. In 7 of the 11 studies, the PD patients were younger and in all of the studies, PD patients were less likely to be African-American. Two studies reported that PD patients were more likely male.^{30,33}

All studies used an intent-to-treat approach. Three used a Poisson regression model,^{30,32,36} 5 used Cox proportional hazards models,^{29,31,33,34} one used a MSM approach,²⁸ 2 used both Cox and MSM models,^{26,35} and one did not specify.²⁷ Two studies included matched-pair data.^{27,29} Additional patient characteristics and details about the analyses are presented in Appendix C, Table 1.

One additional study reported US data.³⁷ This analysis included 17,926 patients either receiving dialysis on January 1, 1992 or starting dialysis during 1992. PD patients were younger and more likely white. An intent-to-treat approach was used with a Cox proportional hazards model. Additional information is provided in Appendix C, Table 1.

There were 3 reports from ANZDATA^{11,12,38} including 2 cited above because they also included an HHD group.^{11,12} The study dates ranged from 1991 to 2011 with maximum follow-ups of 15 years. Two of the studies included approximately 25,000 incident patients^{12,38} while the third included 6,419 patients.¹¹ Two studies reported that PD patients were older and less likely male.^{11,38} As noted for the HHD/HD comparison above, one study use an “as-treated” approach with a MSM model¹² and another used an “as-treated” approach with a Cox proportional hazards model.¹¹ The third study used an intent-to-treat approach with Cox regression models.³⁸ Appendix C, Table 1 provides more information about these studies.

Four of the registry studies were from Canada – 3 from the Canadian Organ Replacement Register (CORR)³⁹⁻⁴¹ and one from the Institute for Clinical Evaluative Sciences (ICES).⁴² The studies enrolled patients between 1990 and 2006 with maximum follow-up periods ranging from 5 years⁴¹ to 17 years.³⁹ Sample sizes ranged from 6,573⁴² to 46,839³⁹ incident patients. One study reported that the HD patients were older than the PD patients⁴¹ and another reported that there was a higher percentage of HD patients in the age 65 and older category while more PD patients were in the age 35 to 64 year category.³⁹ All of the studies used an intent-to-treat approach with Cox models (Appendix C, Table 1).

The remaining 8 registry reports were from Europe or the UK. Included were reports from the Dutch End-Stage Renal Disease Registry (RENINE),⁴³ the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA),⁴⁴ the Finnish Registry for Kidney Diseases,⁴⁵ the French Renal Epidemiology and Information Network (REIN),⁴⁶ the Lombardy Dialysis and Transplant Registry,⁴⁷ the Romanian Renal Registry,⁴⁸ the Scottish Renal Registry,⁴⁹ and the United Kingdom Renal Registry (UKRR).¹⁴ The studies included incident patient data from 1987 to 2011 with follow-up periods ranging from a mean of 2.4 years⁴³ to a maximum of 25 years.⁴⁹ Sample sizes ranged from 2,475¹⁴ to 16,643.⁴³ Three studies reported that PD patients were younger⁴³⁻⁴⁵ while another reported that PD patients were older.⁴⁶ Three studies reported that PD patients were less likely male^{46,48,49} while a third reported that PD patients were more likely male.⁴³ One study reported that a higher percentage of PD patients were on the transplant wait list.⁴⁵ All of the studies used an intent-to-treat approach with Cox models. Additional information about the studies is reported in Appendix C, Table 1.

One RCT and 2 clinical cohort studies also compared HD and PD. The RCT, completed in the Netherlands, enrolled 38 patients new to dialysis and randomized them to HD or PD.⁵⁰ Patients were followed for a maximum of 5 years. The trial was stopped because of low enrollment, failing to reach the goal of 100 patients. Despite randomization, the HD patients were older.

The clinical cohort studies included the Choices for Healthy Outcomes in Caring for ESRD (CHOICE) study completed in the US⁵¹ and the Netherlands Cooperative Study on Adequacy of Dialysis (NECOSAD).⁵² The CHOICE study enrolled 1,041 incident patients between 1995 and 1998 and followed them for a maximum of 7 years.⁵¹ The PD patients in this study were younger and more likely white. The NECOSAD cohort enrolled 1,222 incident patients and followed them for a maximum of 4 years.⁵³ PD patients were younger and more likely male. Both studies used an intent-to-treat approach with Cox proportional hazards models.

Mortality

Mortality outcomes are summarized in Table 2 with more detailed reporting in Appendix C, Tables 1 and 2. Of the 27 registry studies, 22 reported overall mortality with 12 finding no significant difference in mortality between HD and PD, 4 finding a more favorable outcome for PD, and 6 finding a more favorable outcome for HD.

Of the 11 CMS/USRDS studies, one reported overall mortality (maximum follow-up of 4 years) finding no difference (HR 1.05 [95% CI 0.96, 1.16]).²⁹ By year of follow-up, the difference was not significant during the first year but there was a difference, favoring HD, at 2 years (HR 1.19 [95% CI 1.02, 1.38]).²⁹ Another study with over 23,000 patients reported results at one year and 2 years (but no overall results).²⁶ In that study, there was significantly reduced mortality at both one (HR 0.59 [95% CI 0.44, 0.78]) and 2 years (HR 0.52 [95% CI 0.34, 0.80]) for the PD group. Another study reported reduced overall mortality (maximum follow-up of 6 years) for PD (HR 0.88 [95% CI 0.81, 0.95]).²⁷ Two older studies^{33,36} found increased mortality in the PD group. Follow-up periods were 2 years³³ and one year.³⁶ One study found no difference in mortality over a maximum follow-up of 5 years between PD and HD (HR 1.03 [95% CI 0.99, 1.06]).²⁸ The remaining study did not report overall mortality results.³¹

The other US study reported an overall increased risk of death over one year follow-up with PD (RR 1.32, P = .005).³⁷

Two of the ANZDATA studies favored HD. One reported an increased overall mortality risk (maximum follow-up of 11 years and 9 month) in the PD group (HR 1.10 [95% CI 1.06, 1.16]).¹² The other reported an increased risk in the PD group at one or more years follow-up (HR 1.32 [95% CI 1.26, 1.38]).³⁸ The third study, focused on patients from New Zealand, found no difference between PD and HD in overall mortality although mortality was lower in the PD group during the first 3 years and greater in the PD group at greater than 3 years.¹¹

Among the 4 studies from Canada, 3 found no difference in overall mortality between HD and PD.^{39,41,42} Follow-up periods ranged from maximums of 5⁴¹ to 17³⁹ years. One reported reduced overall mortality (maximum follow-up of 6 years) with PD (mortality rate ratio 0.93 [95% CI 0.87, 0.99]).⁴⁰ All but one of the studies⁴² reported an early survival advantage for PD patients with no difference after 2 to 3 years of treatment.

Of the 8 studies from Europe or the UK, 6 reported no difference in mortality between HD and PD.^{14,43,45,47-49} Follow-up periods were up to 25 years. These studies enrolled patients from 1982 to 2011. In one of the studies, all of the patients were on a renal transplant list at some point after the start of dialysis indicating comparable baseline characteristics.⁴⁹ One study reported reduced mortality (mean follow-up of 1.6 years) in the PD group (HR [PD vs HD] 0.82 [95% CI 0.75, 0.90])⁴⁴ and one reported reduced mortality (maximum follow-up of 7 years) in the HD group (HR [PD vs HD] 1.48 [95% CI 1.33, 1.65]).⁴⁶

Although it is difficult to assess temporal trends due to differences in study populations, length of follow-up reported, and methods of data analysis, publication dates would suggest that a trend may exist. All but 2 studies showing increased mortality with PD compared to in-center HD were published before 2003 while all but 3 studies showing no difference or reduced mortality with PD were published after 2003.

The RCT reported no difference in mortality (HD vs PD) with a maximum follow-up of 5 years.⁵⁰ The adjusted hazard ratio was 3.6 (95% CI 0.08, 15.4, P = .09) with higher mortality in the HD group.

In the CHOICE study, the relative hazard of death (PD vs HD) was 1.61 (95% CI 1.13, 2.30) using a multivariate model and adjusting for demographic characteristics, clinical/treatment factors, and laboratory values.⁵¹ By year of treatment, the relative hazard was 1.39 (95% CI 0.64, 3.06) in the first year and 2.34 (95% CI 1.19, 4.59) in the second year indicating that the risk of death did not differ significantly between PD and HD in the first year of treatment but during the second year, the risk of death for PD patients was significantly higher than for HD patients.

In the NECOSAD study, the one year mortality risk ratio (HD vs PD) was 1.32 (0.80, 2.18).⁵³ There was no difference in mortality for the first 2 years of dialysis. After 2 years, the adjusted risk ratio decreased and favored HD. The authors concluded that long-term use of PD was associated with increased mortality.

Table 2. Mortality – In-center Hemodialysis (HD) vs Peritoneal Dialysis (PD) – Registry and Trial Data

Country/ Region: Number of Reports	Study Years	Patients: Number of Reports or Sample Size	Overall Mortality: Number of Reports			Number of Studies Reporting Effects by:						
			No difference	Favor PD	Favor HD	Age	Gender	Race	BMI	DM	CVD	ESRD Duration
REGISTRY STUDIES												
USA: 12 ^a	1987-2006	Incident: 11 Prevalent: 1 (Matched: 2)	2	2 ^b	3	4	2	3	3	5 ^e	3	
Australia/ New Zealand: 3	1991-2007	Incident: 2	1		2 ^c	3		2	2	2	1	2
Canada: 4	1990-2006	Incident: 4	3	1						1		
Europe/ UK: 8	1987-2011	Incident: 8 (Matched: 1)	6	1	1	3	2			2	1	
RANDOMIZED CONTROLLED TRIALS												
Netherlands: 1	1997-2000	N=38	1									
CLINICAL COHORT STUDIES												
USA: 1	1995-1998	Incident, N=1041			1							
Netherlands: 1	1997-2002	Incident, N=1222	1 ^d									

^a 5 studies reported mortality in subgroups but no overall mortality

^b One study favored PD at 1 year and at 2 or more years (no overall results reported)

^c After 1st year for 1 of the 2 studies

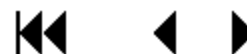
^d Favored HD after 2 years

^e 5 datasets (reported in 7 publications)

Interactions (Appendix C, Table 3)

Age. Ten registry studies assessed interactions between dialysis modality (HD, PD) and age. Significant interactions were reported for 5 studies.^{12,29,32,36,43} In one of the US studies, which demonstrated an overall increase in the risk of death with PD, the risk of death was significantly higher for PD patients than for HD for patients older than 55 years but not for those younger than 55 years.³⁶ Two other US studies evaluated risk above or below age 65 years with a significant interaction favoring HD for patients age 65 and older.^{29,32} A study from Australia/New Zealand reported a significant interaction by age at dialysis inception.¹² A study from the Netherlands reported an age by modality interaction with the survival benefit of PD decreasing with age.⁴³ Five other studies reported either non-significant interactions^{11,26,45,46} or a significant interaction in the first year of dialysis but not after one year.³⁸

Gender. Four studies assessed interactions between modality and gender. One reported that the mortality risk was significantly higher for PD compared to HD for both males and females but the risk was accentuated for females (RR 1.30 for females vs RR 1.11 for males).³⁶ One reported an interaction between dialysis modality and gender for patients with ischemic heart disease or peripheral vascular disease with the survival benefit of PD only observed for male patients.⁴⁴ Two studies reported that the interaction was not significant.^{32,45}



Race. Interactions of modality and race were assessed in 5 studies.^{11,32,36,38,54} Two reported no effect of race.^{36,38} Another reported a mortality benefit for PD in white patients with BMI greater than 30 but not non-white patients.⁵⁴ The significance was not reported. One study reported an interaction effect that was significant for Asian and other categories (relative to white)³² while the fifth study reported different patterns of risk over time (less than 3 years from inception of dialysis vs more than 3 years) for different ethnicity groups.¹¹

BMI. Five studies assessed interactions with BMI.^{11,31,32,38,54} The most recent study reported no significant interaction with between modality and BMI.¹¹ One study found that a BMI of 30 or higher was associated with improved survival for HD patients (HR 0.89) but not PD patients (HR 0.99).³¹ Another study found significantly increased mortality risk for PD in the 3 highest BMI groups (BMI of 23.5 or higher) in patients with diabetes, while for patients with no diabetes the mortality risk was significantly higher only in the highest BMI group (BMI greater than 30).⁵⁴ One study reported a non-significant interaction of BMI and mortality between 90 and 365 days of treatment but a significant interaction after 365 days.³⁸ The effect sizes were clinically similar across all BMI categories, however. The fourth study found significant interactions between treatment modality and overweight (BMI 25.1 to 30) and obese (BMI greater than 30) but not underweight (BMI less than 18.5).³²

Diabetes. Interactions between modality and diabetes were assessed in 12 reports from 10 datasets.^{12,26,29,32,33,36,38,42,43,45,54,55} The interaction was not significant in 4 studies^{26,38,42,45} while 5 studies reported higher mortality risk (PD vs HD) in patients with diabetes.^{12,29,32,36,43} Another study reported that across levels of BMI, patients with diabetes tended to have increased risk of mortality with PD compared to patients without diabetes.⁵⁴ Additional analyses of this data focused on patients with coronary artery disease⁵⁵ or congestive heart failure.³³ Patients with CAD or CHF and diabetes had higher mortality with PD compared to patients without diabetes.

Cardiovascular Disease. Six reports (2 from the same dataset) reported on interactions between cardiovascular disease and modality.^{11,29,32,33,46,55} As noted above, 2 analyses from one study⁵⁴ focused on coronary artery disease (CAD)⁵⁵ and congestive heart failure (CHF).³³ For patients with diabetes, the mortality risk was greater for PD regardless of CAD status⁵⁵ or CHF status.³³ For patients without diabetes, mortality was elevated in the CAD group but not the no-CAD group⁵⁵ and in the CHF group but not the no-CHF group.³³ Significant interactions with cardiovascular disease were reported in 2 other US studies^{29,32} while a French study and a New Zealand study reported non-significant interactions.^{11,46}

Duration of ESRD Therapy. One study reported on duration of ESRD therapy finding a significant statistical interaction between ESRD vintage and mortality risk. It was noted that there was little clinical significance.³⁸ Another study reported a non-significant interaction.¹¹

Other Outcomes

Cardiovascular Events (Appendix C, Table 1)

Five registry studies reported on cardiovascular events.^{12,35,46-48} One study from Italy focused on the development of *de novo* cardiovascular disease.⁴⁷ At baseline, there were no significant differences between the HD and PD groups in the percentages of patients with a history of coronary heart disease, myocardial infarction, or chronic heart failure. During the study period (maximum follow-up of 4 years), 11.4% of the deaths in the PD group and 21.1% of the deaths

in the HD group were due to cardiac causes although it was noted that these numbers did not take into consideration patients who switched dialysis modalities. The relative risk of developing *de novo* cardiovascular disease (PD vs HD) was 1.06 [95% CI 0.79, 1.43]). Similar risks were reported for ischemic heart disease and congestive heart failure.

Three studies, one from Australia/New Zealand,¹² one from Romania,⁴⁸ and one from France,⁴⁶ reported cardiovascular mortality. In the first study, 54% of deaths in the PD group and 47% of deaths in the HD group were due to cardiovascular causes (significance not reported).¹² In the second study, the difference in cardiovascular mortality was not statistically significant (PD 47%, HD 49%, $P = .70$)⁴⁸ while in the third study, a significant difference was reported (PD 40%, HD 35%, $P = .04$).⁴⁶

A study from the US reported risk of cardiovascular mortality (PD vs HD) for patients age 55 and older.³⁵ In patients with diabetes, both males and females receiving PD had a reduced risk of cardiac death (RR 0.90 for both) relative to males age 55 and older receiving in-center HD. In patients without diabetes, the pattern of results was similar with relative risk of 0.70.

Hospitalization (Appendix C, Table 4)

None of the registry studies reported hospitalization. A NECOSAD publication reported that 46% of PD patients and 58% of HD patients were hospitalized at least once over a follow-up period that ranged from 5 months to 7.8 years.⁵² A longitudinal study from the US with 181 incident patients (119 HD, 62 PD) reported higher total admissions per year at risk in the HD group (2.4) compared to the PD group (1.4) ($P < .0001$).⁵⁶ Admissions for infection per year at risk were higher for PD patients (0.42) than HD patients (0.29) ($P = .02$).⁵⁶ A second US study with 177 patients also reported more hospitalizations (1.5 vs 0.4, $P < .01$) and more hospital days (12.2 vs 2.4, $P < .05$) over follow-up of up to 15 months in HD patients compared to PD patients.⁵⁷ In a UK study of patients who started dialysis at age 70 years or older, hospitalization did not differ between HD (2.0 events/1 patient-year) and PD (1.9 events/1 patient-year) ($RR_{PD \text{ vs } HD} 0.97$ [95% CI 0.77, 1.22]).⁵⁸ A cross-sectional study from Canada reported no difference in mean hospitalizations in the past year for HD (1.68) and PD (1.43) patients.²⁴

Quality of Life, Cognition, Depression (Table 3, Appendix C, Table 4)

None of the registry studies reported quality of life or related outcomes. We identified a 2011 systematic review that included published and grey literature studies (English language only) through July 2010, enrolling adults on either in-center HD or PD, and using a validated tool to assess and compare quality of life for HD and PD patients.⁵⁹ Outcomes for both generic (*ie*, broad aspects of quality of life, suitable for different locations and different cultures such as the SF-36) and disease-specific quality of life tools were reported.

Twenty-six studies from the US, Europe/UK, and the Asia/Pacific region were included. Twenty were cross-sectional studies, 4 were cohort studies, and 2 were retrospective analyses. Of the 12 studies that used the SF-36, only 4 reported physical and mental health component summary scores. A significant difference, with better health in the PD group, was observed for both scores in one cross-sectional study from Turkey enrolling 115 patients. This study also reported significant differences, favoring PD, for the 8 individual dimensions of the SF-36. One other study, a cross-sectional study from China with 1,062 participants, reported significant differences, favoring PD, for 6 of the 8 individual dimensions (bodily pain, general health

perception, vitality, social functioning, role limitations due to emotional functioning, and mental health). Two additional cross-sectional studies, one from the Netherlands with 1,553 participants and one from Taiwan with 244 participants, reported significant differences favoring PD for the bodily pain and role limitations due to emotional functioning dimensions. Of 5 studies reporting kidney disease-specific quality of life with the 11-item KDQOL instrument, significant differences favoring PD were found for 4 of 11 dimensions in a cross-sectional study from Denmark (N=130), 4 of 9 dimensions assessed in a cohort study from France (N=387), and 3 of 3 dimensions assessed in a cross-sectional study from the US (N=226). Other quality of life tools were used in only one or 2 studies and generally no differences were observed between HD and PD patients.

This review was of average quality based on the AMSTAR criteria.⁶ Although it was reported that study quality was assessed, the quality ratings were not provided nor used in developing the conclusions for the review. Eleven studies were excluded from the analysis because of either weak design or irrelevance to the topic but no additional information was provided. Little information was provided about the study populations of the included studies and the timing of the quality of life assessment was not reported. Results were provided for only some of the studies reported to have used a particular quality of life assessment tool and little information was provided about tools other than the SF-36 and KDQOL.

We supplemented the information from the Boateng and East review⁵⁹ with more complete data from the 3 US studies included in the review (Table 3) and with data from studies identified in our search of MEDLINE and other sources but not included in the review (Appendix C, Table 4). The 3 US studies, all rated as high risk of bias, found few differences between HD and PD patients in overall measures of physical or mental function with mixed results for individual dimensions (Table 3).⁶⁰⁻⁶²

Among the studies not included in the review, the small RCT (n=38) from the Netherlands found no significant difference in the quality adjusted life year scores for the PD and HD groups (54 vs 59; adjusted difference 3.1 [95% CI -9.9, 16.1], P = .63).⁵⁰

Among 949 patients from the CHOICE study, higher overall functional support (assessed with the Medical Outcomes Study Social Support Survey) was higher for the PD patients (81 vs 76, P = .002).⁶³ Higher scores were reported for the emotional support, tangible support, and positive social interaction domains but not for the affectionate support domain. Social support in the highest tertile was significantly associated with the chance of receiving PD (P = .02).⁶³

Several reports with subsets of the NECOSAD cohort addressed quality of life outcomes. One (n=161) reported no difference between HD and PD in illness consequences or whether treatment controls the illness (both measured with the Brief Illness Perception Questionnaire).⁶⁴ Based on responses to the Treatment Effects Questionnaire, HD patients perceived more consequences of treatment than PD patients (P = .01).⁶⁴ Another study (n=528) reported that the effect of social support on mortality was similar for HD and PD patients.⁶⁵ A third study (n=228) reported a significant adjusted mean difference over time in physical quality of life (SF-36) favoring HD (1.6 [95% CI 0.04, 3.20], P = .04) but no difference in mental quality of life.⁶⁶

Several longitudinal or cross-sectional studies, not included in the existing reviews, also provided quality of life outcomes. A longitudinal study from the UK reported no significant differences in SF-36 Physical Component, SF-36 Mental Component, or KDQOL Symptom scores at 6 or 12 months follow-up between HD and PD patients who were 70 years of age or

older at the start of dialysis.⁵⁸ One cross-sectional study from the UK reported scores for the Treatment Effects Questionnaire, Beck Depression Index, and Cognitive Depression Index.²² No differences were noted between in-center HD and PD. A 2002 study from the UK found mixed results for different quality of life instruments.⁶⁷ On the EuroQol EQ-5D, differences between in-center HD and PD patients were not significant. Using the Kidney Disease Quality of Life instrument, patients receiving PD scored significantly higher on effects of kidney disease, burden of kidney disease, and cognitive function but lower for sexual function. On the SF-36, PD patients had higher scores for the mental component summary but not the physical component summary. A 1999 study from the UK (cited above in the in-center HD vs HHD analysis) reported scores on components of the SF-36.²³ Differences across groups (HHD, in-center HD, and PD) were noted for Physical Functioning, Role Physical, Social Functioning, and Role Emotional. The Canadian study (also cited above in the in-center HD vs HHD analysis) reported a non-significant difference between HD and PD in scores on the Self-Anchoring Striving Scale but significantly lower scores for HD vs PD on the Index of Well-Being and the Health State Utility/Time Trade-off assessment.²⁴ A study from the US reported that the risk of moderate to severe cognitive impairment for patients receiving either PD or in-center PD was significantly higher than that for patients age 55 and older without CKD.⁶⁸

A second average-quality systematic review presented quality of life utilities.⁶⁹ Utilities represent the strength of a patient's preference for specified health-related outcomes with values ranging from 0 (death) to one (full health). Some studies included in the review assessed utilities directly. For others, utilities were derived from SF-36 scores. The review included patients ranging from pre-treatment CKD to kidney transplant; 69% of the utilities evaluated in the review were from studies of dialysis. The mean utility estimate for HD (including both in-center HD and HHD) was 0.69 (95% CI 0.59, 0.80) while the estimate for PD was 0.72 (95% CI 0.62, 0.83). Although 0.03 is considered to be the minimum clinically important difference for utility scores, the test for interaction was not significant ($P = .08$).

Studies of life participation activities were reported in a high-quality systematic review.⁷⁰ The activities of interest were physical function (eg, activities of daily living, self-reported physical functioning with the SF-36), travel abilities or restrictions, ability to engage in recreational or social activities, freedom (eg, perceived independence, ability to perform usual tasks), and work outcomes (eg, employment or working capacity). The review included English language cohort and cross-sectional studies published between 1980 and April 2012 and using a variety of outcome measures. For the comparison of HD and PD, there were 39 studies. Of 41 measures of physical function (some studies reporting more than one measure), only 10 showed a significant difference between HD and PD with 3 favoring HD and 7 favoring PD. Of 2 measures of travel, there was one significant difference favoring HD. There were 18 measures of recreation, 4 with significant differences favoring PD. Of 8 measures of freedom, one favored HD and one favored PD. Similarly, of 13 measures of work, 2 favored HD and 2 favored PD. The authors reported that the results were consistent across study designs, locations (US vs non-US), quality rating (appropriate adjustment for confounders vs no or minimal adjustment), and year of publication (1980-1990, 1991-2000, 2001-2012).

Change in Dialysis Modality (Appendix C, Table 1)

Seven registry studies reported changes in dialysis modality. A USRDS study reported that 6% of HD patients switched to PD and 57% of PD patients switched to HD during the 2 year follow-up period.²⁶ A second USRDS reported similar findings; over a maximum follow-up of 5 years,

4% of HD patients switched modality at least once compared to 46% of PD patients.³¹ A Canadian study reported technique survival for PD and HD was similar up to 10 months follow-up.³⁹ After 10 months and through 60 months of follow-up, technique survival was lower for the PD group. Another Canadian study found greater risk of technique failure with PD compared to HD (186/1000 person-years vs 165/1000 person-years; RR 1.15 [95% CI 1.01, 1.31]).⁴¹ In 2 European studies, 25% (over 3 years)⁴⁴ and 11% (over 7 years)⁴⁶ of PD patients switched modalities compared to 4%⁴⁴ and 1%⁴⁶ of HD patients. One study reported median time at the modality switch was 12 months for PD and 4 months for HD.⁴⁶ A third European study reported that 0.6% of HD patients and 0.9% of PD patients changed dialysis modality during the follow-up period of up to 5 years.⁴⁸ The modality change occurred at a median of 11 months for the HD to PD patients and at a median of 13 months for the PD to HD patients. In the CHOICE cohort study, 25% of the patients who were initially on PD switched modality at least once over maximum follow-up of 7 years compared to 5% of those who were initially on HD.⁵¹ From the NECOSAD cohort, 2 year technique survival was 96% for HD patients and 74% for PD patients.⁵³

Transplantation (Appendix C, Table 1)

Transplantation was reported in 6 registry studies. One USRDS study reported that transplant rates during the first 2 years of dialysis were 6% for HD and 18% for PD.²⁶ Another USRDS study reported the hazard ratio for renal transplant over up to 6 years follow-up (PD vs HD) was 1.48 (95% CI 1.29, 1.70).²⁷ A study from Canada also reported higher transplantation over a maximum of 5 years follow-up in PD compared to HD (RR 1.16, 95% CI 1.06, 1.28).⁴¹ Two European studies found comparable percentages of transplants between PD and HD; 17.9% (PD) and 17.7% (HD) in a multinational study with maximum follow-up of 3 years⁴⁴ and 2.3% (PD) and 3.5% (HD) in a study from France with maximum follow-up of 7 years.⁴⁶ The mean time to transplant after start of RRT was 25 months for the PD patients and 22 months for the HD patients.⁴⁶ Another European study, with maximum follow-up of 5 years, reported lower transplantation in the PD group (0.4%, median time 9.5 months) than in the HD group (2.1%, median time 11 months).⁴⁸ In the NECOSAD cohort, 15% of the original HD cohort and 21% of the original PD cohort underwent renal transplant during a follow-up period of up to 4 years.⁵³

Table 3. US Studies Included in Systematic Review (Boateng 2011)

Author, Year Modalities	Inclusion Criteria	Patient Characteristics	Quality of Life	Other Outcomes
Kutner 2000 ⁶⁰ PD, HD Risk of Bias: High Selection bias: inadequate Blinding: inadequate ITT: unclear Attrition bias: inadequate Selective outcome reporting: no	Age ≥20, started on HD or PD July 1996-August 1997, not cognitively impaired, able to communicate in English or Spanish	N=226 (154 HD, 72 PD) Age (yr): 56* Gender (% male): 53 Race (%): white 46, black 48 *PD patients were younger and less likely black	-Baseline SF-36 (mean of 67.3 days on dialysis): no significant differences between HD and PD patients for any of the 8 dimensions -KDQOL: being on PD was associated with higher “staff encouragement” (the extent to which the dialysis staff encourages the patient to be independent and supports the patient in coping with kidney disease) and “satisfaction with care” received for dialysis	PD patient (vs HD) associated with ability to complete a greater number of chair rise cycles (sit-to-stand-to-sit)
Diaz-Buxo 2000 ⁶¹ PD, HD Risk of Bias: High Selection bias: inadequate Blinding: unclear ITT: unclear Attrition bias: unclear Selective outcome reporting: no	Fresenius Medical Care North America patient, completed SF-36 in 1996	N=18,015 (16,755 HD, 1,260 PD) Age (yr): 59* Gender (% male): 52 Race (%): white 54 *PD patients younger and more likely white	-SF-36 PCS: no difference between HD (33.3±10.4) and PD (33.7±10.6); no difference when adjusted for case mix or for case mix plus laboratory variables -Physical function dimensions: HD scores lower than PD for physical function (unadjusted) and bodily pain (unadjusted and adjusted); HD scores higher for general health (unadjusted) -SF-36 MCS: no difference between HD (47.5±11.7) and PD (47.9±11.6); better scores for PD after adjustment for case mix (P = .015) and case mix plus laboratory variables (P = .014) -Mental function dimensions: HD scores higher than PD scores for vitality (unadjusted and adjusted); HD scores lower than PD scores for role-emotional and mental health (unadjusted and adjusted) and social functioning (adjusted)	NR
Wu 2004 ⁶² (CHOICE) PD, HD Risk of Bias: High Selection bias: inadequate Blinding: N/A ITT: yes Attrition bias: inadequate Selective outcome reporting: no	Age ≥18, able to speak English or Spanish, excluded HHD patients; oversampled PD patients	N=928 incident patients (698 HD, 230 PD) who completed baseline CHEQ (89% of total study sample) Age (yr): 58* Gender (% male): 53 Race (%): white (68), black (28), other (5)* *PD patients younger and more likely white	-585 completed CHEQ at 1 year -Adjusted mean change over 1 year: a. HD patients showed greater improvement in 8 domains of SF-36 compared to PD; only “physical functioning” and “general health” domains were significantly different from PD at 1 year b. HD patients showed significantly greater improvement in sleep domain of CHEQ; PD patients showed significantly greater improvement in finance domain -Adjusted ORs for improvement in health status (PD vs HD): SF-36 Physical Composite 0.79 (0.52, 1.20) SF-36 Mental Composite 0.95 (0.62, 1.45) CHEQ Global QOL 0.90 (0.56, 1.45)	NR

CHEQ = CHOICE Health Experience Questionnaire; KDQOL = Kidney Disease Quality of Life instrument; MCS = mental health component summary; N/A = not applicable; PCS = physical component summary



Adverse Events (Appendix C, Table 4)

A report from the NECOSAD cohort identified adverse events.⁷¹ Incidence rate ratios (HD vs PD) for the study period (maximum follow-up of 10 years) were 1.65 (95% CI 1.34, 2.03) for total infections, 4.10 (95% CI 3.06, 5.58) for dialysis technique-related infections, and 0.56 (95% CI 0.40, 0.79) for non-dialysis technique-related infections. A longitudinal study (mean follow-up 1.3 years) from Canada with 369 patients reported fewer access-related invasive interventions in the PD group than the HD group (1.0 vs 1.4 per patient-year; Rate Ratio 0.72 [95% CI 0.53, 0.96]).⁷² A US study with 181 patients found no difference between HD and PD in median total infections per time at risk or infection rate per year at risk.⁵⁶ There was a higher bacteremia/fungemia infection rate in the HD group and a higher peritonitis rate in the PD group (both $P < .001$). A longitudinal study (follow-up of up to 19 months) from the Netherlands reported pancreatitis in one HD patient (0.4%) and 7 PD patients (5.4%) ($P < .001$).⁷³ A study from Belgium with a 10 year follow-up period reported reasons for switching dialysis modalities.⁷⁴ Among 35 patients who switched from HD to PD, cardiovascular problems were reported by 40%, access problems by 25%, and blood pressure problems by 12%. Among 32 patients who switched from PD to HD, peritonitis or exit-site infections were reported by 50%, adequacy and/or ultrafiltration problems by 25%, and extraperitoneal leakage of dialysis fluid by 11%. A cross-sectional study from the UK reported gastrointestinal symptoms.⁷⁵ Both HD and PD patients experienced a higher rate of symptoms compared to hospital outpatient controls and community controls with abdominal pain in 72% of HD patients and 65% of PD patients, laxative use in 43% of HD patients and 79% of PD patients, and irritable bowel syndrome in 21% of HD patients and 33% of PD patients.

Peritoneal Dialysis Compared to In-Home Hemodialysis

Two studies provided a comparison of PD and HHD.^{9,14} One study was from the US⁹ and the other from England and Wales.¹⁴ Enrollment years and follow-up durations were similar ranging from 1995 to 2005 and 9 years, 3 months to 10 years, respectively. Sample sizes differed with the US study including 38,894 incident patients (1,641 out-of-center HD [mostly home])⁹ and the UK study including 1,125 incident patients (225 HHD).¹⁴ In the US study, HHD patients were more likely non-white compared to PD patients⁹ while in the UK study, HHD patients were more likely white.¹⁴ Both studies used Cox proportional hazards models with an intent-to-treat approach.

The US study found no significant difference in mortality risk between the 2 modalities (HR 1.04 [95% CI 0.98, 1.11]) (Table 4 and Appendix C, Table 1).⁹ The UK study reported a significant survival benefit associated with HHD (HR 0.61 [95% CI 0.40, 0.93]).¹⁴ The benefit was observed after adjustment for patients from the HHD group being more likely wait-listed for kidney transplant.

Neither of the studies reported interactions with age, gender, race, BMI, diabetes, cardiovascular disease, or duration of ESRD therapy, although the US study did note that the results did not differ among patients more likely to reside at home (based on age, ability to ambulate and transfer independently, and diabetes and/or cardiovascular disease) or more likely to reside in a long-term care facility.⁹

Table 4. Mortality – Home Hemodialysis (HHD) versus Peritoneal Dialysis (PD) – Registry Data

Country/ Region: Number of Reports	Study Years	Patients: Number of Reports or Sample Size	Overall Mortality: Number of Reports			Number of Studies Reporting Effects by:						
			No difference	Favor PD	Favor HHD	Age	Gender	Race	BMI	DM	CVD	ESRD Duration
REGISTRY STUDIES												
USA: 1	1995-2004	Incident: 1	1									
UK: 1	1997-2005	Incident: 1			1							

Other Outcomes

Cardiovascular Events, Hospitalization, Quality of Life, Cognition, Depression, Transplantation

Neither of the studies reported these outcomes for HHD compared to PD.

Change in Dialysis Modality (Appendix C, Table 1)

As noted above in the section describing studies comparing HHD to in-center HD, the study from the UK reported that median technique survival for HHD was 18 month (IQR 9 to 33 months).¹⁴ Most patients underwent a kidney transplant or switched to in-center HD.

KEY QUESTION 2A. Do results differ depending on whether peritoneal dialysis was the initial therapy or the therapy used following failed in-center dialysis?

A prospective cohort study from Spain enrolled 489 incident PD patients.⁷⁶ Average follow-up was 13.4 months. Ninety-five (19%) had started dialysis on HD. The mortality rate was higher in patients that changed from HD to PD compared to those who initiated RRT with PD (11.5% vs 4.6%, $P = .009$). In a longitudinal study from Poland, 264 PD patients (67 of whom transferred to PD after a median of 18 months [range 3-268] on HD) were followed for a median of 21 months.⁷⁷ No significant difference was observed in survival for the transferred patients versus the initial PD patients (RR 1.68 [95% CI 0.87, 3.22]). The result was similar for the combination of patient and technique survival (RR 1.45 [95% CI 0.89, 2.37]). A registry study from the US with 40,869 patients and follow-up of one to 4 years reported that survival was higher for patients who initially received PD compared to those who transferred from HD.⁷⁸ At one year, the percentage of patients surviving was 86.7% in the initial PD group compared to 83.9 in the transfer to PD group. At 4 years, the values were 56.7% and 53.1%, respectively. The hazard ratio for patient survival for patients new to dialysis versus transfer from HD was 0.73 ($P < .0001$). It was noted that duration of ESRD was likely longer for the patients transferring from HD. Technique survival was longer for the initial PD patients. The hazard ratio for technique survival (new to dialysis versus transfer from HD) was 0.79 ($P < .0001$). Patients new to dialysis were more likely to undergo transplantation (HR 1.31, $P < .0001$). Details of these studies are presented in Appendix C, Tables 4-6.

Risk of Bias for Key Question 2

As noted for Key Question 1, we did not assess the risk of bias of individual registry studies. Registry studies are typically considered high risk of bias due to issues with selection bias and inability to assess and include all potential confounders in analyses. There was one high risk of bias RCT that addressed KQ2. Of 8 clinical cohort reports, 4 were rated as high risk of bias and 4 as moderate risk of bias. There were 7 longitudinal studies – 2 high risk of bias and 5 moderate risk of bias. All of the cross-sectional studies (k=6) were rated high risk of bias. Additional information is presented in Appendix C, Table 2.

KEY QUESTION 3. What are the a) health care system, b) provider, and c) patient factors associated with selection of and technique survival for home-based dialysis (including peritoneal dialysis)?

Summary of Findings

- Twenty-two articles (21 studies, 8 from the US) provided information on factors associated with selection of PD and 5 articles (none from the US) addressed factors associated with selection of HHD.
- For PD selection, the following factors were reported:
 - *Health Care System Factors:* One US cross-sectional study reported that provision of home-based dialysis (including PD) was more likely in larger dialysis facilities (defined as 62 patients or more) with more years of facility Medicare certification and facilities with a higher population of employed 18 to 54 year old patients. Home-based dialysis was less likely at facilities in more rural areas, facilities offering evening care, and facilities with higher treatment capacity (based on number of patients, number of HD stations, and availability of a late shift).
 - *Provider Factors:* Several studies found that provision of patient education about dialysis modalities and a determination of medical (including comorbid conditions and decreased strength, manual dexterity, vision, or hearing) and psychosocial suitability (including fear of self-cannulation, anxiety, decreased cognition, psychiatric conditions, or history of non-compliance) for PD were associated with greater selection of PD. No studies reported on provider factors such as provider age, training, knowledge about PD, etcetera.
 - *Patient Factors:* Autonomy, ability to travel, and compatibility with employment were identified as positive features of PD. Conversely, lack of understanding, living alone, lack of space in the home, inability to perform PD in the place of residence, fear of social isolation, fear of inability to perform PD, and preference for medical supervision were patient barriers to selection of PD.
- For HHD, the following factors were reported:
 - *Health Care System Factors:* As noted above, dialysis facility size, geographic location, and years of certification were all factors in provision of any home-based dialysis.
 - *Provider Factors:* From a provider perspective, patients with medical contraindications, psychosocial contraindications), unsuitable living conditions (including HHD not permitted, overcrowding, dampness/mold growth), lack of support in the home, and unplanned start or shorter pre-dialysis care by a nephrologist were less likely to be suitable for HHD. Providers with greater numbers of HHD patients reported having a dedicated education team.

- *Patient Factors*: Patient-reported barriers to and advantages of HHD were similar to those noted above for PD.
- Fifteen studies (8 from the US) reported factors associated with PD technique failure (the inverse of technique survival – a switch from PD to in-center HD):
 - *Health Care System Factors*: Patients from larger clinics had lower technique failure.
 - *Provider Factors*: No studies reported on provider factors associated with PD technique survival.
 - *Patient Factors*: African-American or indigenous race, increased BMI or obesity, elevated systolic blood pressure, use of HD before switching to PD, and peritoneal dialysis catheter problems were associated with higher rates of technique failure but each factor was reported in 4 or fewer of the 14 included studies. Mixed results were found for presence of diabetes, age, gender, distance from clinic/nephrologist, and need for assisted PD.
- Five studies (none from the US) reported factors associated with HHD technique failure:
 - *Health Care System Factors*: No studies reported on health care system factors associated with HHD technique survival.
 - *Provider Factors*: No studies reported on provider factors associated with HHD technique survival.
 - *Patient Factors*: Interference with home life, lack of carer support, caregiver anxiety, inability to perform cannulation, medical issues (including diabetes and access problems), and increased age were associated with increased technique failure in 4 studies; one identified no significant predictors of technique failure. Another study reported no difference in a composite outcome of time to all-cause hospitalization, technique failure, or death in patients categorized as dependent on or independent of assistance with nocturnal HHD.

Health Care System Factors (Appendix C, Table 5)

One study reported on facility factors associated with the provision of home-based treatment (either HHD or PD).⁷⁹ The cross-sectional study, done in the US, surveyed 4,653 dialysis facilities. Overall, 7.1% of patients (range across facilities 0% to 100%) were on home-based dialysis. Higher provision of home-based dialysis was associated with larger dialysis facilities (≥ 62 patients vs < 62 patients), more years of facility Medicare certification, a higher percentage of employed patients, and a higher percentage of patients between ages 18 and 54 years. Lower provision of home-based dialysis was associated with more rural location, location in a geographically larger zip code area, location in a zip code of high population density, facility offering a shift starting at 5 pm or later, facility that is part of a chain, facility with higher treatment capacity (determined by number of patients, number of stations, and presence or absence of a late shift), and higher percentage of black patients. “For-profit” status was not significantly associated with home-based dialysis. Lack of resources to support home-based

dialysis in smaller, more rural areas and unmeasured confounding factors may account for these findings.

Another study provided information on training time.⁸⁰ All 87 patients in the study received training on HHD; those randomized to nocturnal HHD underwent additional training. Eight patients were excluded from the analysis of training time. The mean number of training sessions was 28 (range 11 to 59) but no significant difference was noted in training time required for conventional HHD versus nocturnal HHD. Less training time was needed for patients with experience in self-care or both self-care and cannulation while a higher comorbidity score and higher age were related to increased training time required. Training time needed was not related to tests of cognition, education level, or SF-36 Physical Function.

Provider Factors/Provider Perspective (Appendix C, Table 5)

Peritoneal Dialysis

Selection

An Australian study asked nephrologists and chronic kidney disease (CKD) coordinators about information provided to CKD patients prior to selecting a dialysis modality.⁸¹ Among 588 patients who progressed to dialysis, 17.5% did not receive information about treatment options. Patients known to the nephrologists for more than 3 months and patients treated at smaller renal units (< 100 patients) were more likely to receive information. Reasons for not providing information about PD included medical/surgical contraindications, unsuitable living conditions, low literacy, psycho-social contraindications, refusal by patient or family, option not available via service provider, and acute presentation.

A multidisciplinary team (nephrologist, pre-dialysis nurse, PD nurse and/or acute care nurse, social worker) determined contraindications, barriers to self-care, and availability of support in the home for 497 Canadian ESRD patients who had already undergone a minimum of one dialysis treatment.⁸² Medical (obesity, abdominal scarring, ascites, diverticulitis, abdominal hernia) and social (residence or work did not permit PD) contraindications to PD were identified for 110/497 (22%). Barriers to self-care were identified for 245/387 (63%). Patient with barriers were older, more likely female, of lower weight and BMI, more likely to have a cardiovascular condition or cancer, and more likely to have started dialysis as an inpatient and at a higher eGFR. Barriers were categorized as physical (decreased strength, manual dexterity, vision, or hearing, immobility, poor health, or poor hygiene) or cognitive (language, history of non-compliance, psychiatric condition, dementia/poor memory). Among patients with barriers to self-care, those with family support were more likely to be eligible for PD (OR 3.1 [95% CI 1.6, 6.1]) and more likely to utilize PD (39% vs 23%, P = .009).

An earlier study from the same research group also used a multidisciplinary team to identify medical, psychological, and social conditions that could be barriers to PD.⁸³ A control group was included and consisted of patients who lived in regions without home care support. Of the 134 incident patients enrolled, 108 (81%) had at least one medical (decreased strength, manual dexterity, vision, or hearing, or immobility), psychological (anxiety, decreased cognition, psychiatric condition, history of non-compliance) or social (living alone and requiring assistance, residence or nursing home doesn't permit/support PD) barrier to PD. Each condition acting as a barrier reduced the odds of being eligible for PD. There was no difference in the likelihood of

choosing PD or the utilization of PD based on the availability of home care. Female patients and those receiving pre-dialysis care (at least 4 months of nephrology care) were more likely to choose and utilize PD. Patients living in a region with home care assistance, choosing PD, and consenting to follow-up had a mean rate of 4.6 home care visits per week. There were no differences in hospitalizations, modality switches, or deaths among patients receiving assisted PD compared to other dialysis modalities.

Nephrologists of 1,347 patients in the NECOSAD cohort were asked to provide information on patient contraindications for either PD or HD.⁸⁴ Among 225 patients with medical contraindications to PD, previous major abdominal surgery was the most common (38%) followed by cystic kidneys (7%), poor lung function (6%), chronic inflammatory bowel disease (4%), poor cardiac condition (4%), obesity (2%) and “other” (30%). Of 46 patients with medical contraindications to HD, poor cardiac condition was identified for 52%, acute start to dialysis for 7%, and “other” for 41%. There were 150 patients with social contraindications to PD. Most common was incapable of performing PD exchanges themselves (77%) with “other” for 23%. There were 4 patients with social contraindications to HD, all classified as “other.”

Another study provided nephrologists with patient scenarios and asked whether they would recommend HD or PD.⁸⁵ Responses from 271 nephrologists (53% response rate) were analyzed. The mean age of the nephrologists was 46 years, 85% were male, and 72% were white. Thirty-five percent responded that they were equally trained in HD and PD while 61% were trained mostly in HD. Based on the scenarios, the nephrologists were significantly more likely to recommend PD for males, patients 51 to 65 years (compared to 30 to 50 years), patients who were compliant with treatment, patients with residual renal function above 250 ml/d of urine, and patients with an ejection fraction above 25%. They were less likely to recommend PD for patients with weight of 200 pounds or greater, patients with diabetes, and patients living alone. Race or HIV status did not independently influence the modality recommendations. Several conditions were not incorporated into the scenarios and were addressed separately. The percentage of nephrologists recommending HD over PD for different conditions was as follows: inflammatory bowel disease (96%), substance abuse (94%), malnutrition (93%), pregnancy (83%), hepatitis (40%), and myocardial infarction (33%). Ninety-eight percent of nephrologists rated patient involvement as extremely or very important followed by the nephrologist (91%), nurses and social workers (70%), family (65%), and other clinicians (12%).

A study from Canada identified reasons why patients were directed to a particular modality (PD or HD).⁸⁶ Of 150 patients, HD was recommended for 31 for social reasons (65%), unusable abdomen (29%), awaiting liver transplant (3%), or age (3%). PD was recommended for 14 patients due to cardiovascular disease (71%), difficult vascular access (21%), or residence too far from center (7%). PD was also recommended for 31 patients because they were diabetic. Fifty-five percent chose PD and 45% chose HD, primarily for social reasons. There were 74 patients with no specific condition and who were allowed free choice. Fifty percent chose HD and 50% chose PD. There was no gender preference for HD or PD.

Home Hemodialysis

Selection

A recent study reported results from survey of health practitioners who visited the Nephrology Dialysis Transplantation-Educational Web site.⁸⁷ The majority (61%) of responses were from Europe with 8% from North America. Among those who reported having HHD patients, the median number was 6 (range 1-150). Practitioners from dialysis units with more than 6 HHD patients were more likely to have a dedicated education team, more likely to place patients' choice of modality above all other factors, more likely to offer choice of HHD at all stages of CKD, and more likely to believe the evidence supporting extended dialysis schedules. Practitioners from facilities that had HHD patients were more likely to see no financial disadvantage, were more likely to believe the evidence for extended HHD, and had higher expectation of the proportion of patients who could do HHD.

The principal investigator and study coordinator from each of the 8 sites of the FHN Nocturnal Trial (nocturnal HHD compared to conventional HD) were asked to complete a survey focused on barriers to HHD.⁸⁰ The most common perceived barriers to patients electing to choose HHD (reported by > 66% of respondents) were lack of motivation, patients comfortable in-center, fear of self-cannulation, fear of needles falling out or catheter disconnecting, fear of inability to sleep during nocturnal dialysis, high level of comorbid disease, lack of family/partner support, fear of machine, and fear of inability to learn procedures. Home renovation costs were subsidized by outside sources so were not perceived as a barrier. The most common perceived incentives (reported by > 66% of respondents) were flexible scheduling, flexible prescription, less travel to dialysis unit, more liberal diet (with nocturnal HHD), partner encouragement, influence of other HHD patients, more privacy, putative improvement in well-being, and dissatisfaction with current therapy.

A survey of nurses from one health network in Canada included both home dialysis nurses (HHD, PD, and pre-dialysis clinic) and HD nurses.⁸⁸ The home dialysis nurses thought HHD was strongly preferred for working patients or students. The in-center HD nurses thought HD was strongly preferred for patients with poor socioeconomic status, multiple chronic illnesses, and no caregiver or social support. Home dialysis nurses thought that HHD benefited patient quality of life and survival and was lower in cost for patients and the healthcare system. HD nurses thought that HD was preferred for lower risk of catastrophic events. Physicians were rated as having the most influence on patients' choice of modality by 87% of the home dialysis nurses and 57% of the HD nurses.

The Australian study of information about treatment options (cited above in the PD section) also provided information about HHD.⁸¹ Reasons for not providing information about HHD included medical/surgical contraindications, unsuitable living conditions, low literacy, no social/community support at home, psycho-social contraindications, and patient/family refusal. HHD patients were more likely known to the nephrologist for 3 months or longer and more likely to have a caregiver with them at information sessions.

Patient Factors (Table 5 and Appendix C, Table 5)

Peritoneal Dialysis

Selection

An RCT (n=70) from Canada compared outcomes following an educational intervention (written manuals, videos, small group session) or standard care.^{89,90} The goal of the intervention was to increase patient selection of self-care dialysis defined as PD, HHD, and self-care HD. At baseline, there was no significant difference between the groups in the percentage of patients intending to start self-care dialysis. At completion of the study, the difference was significant (82% of the intervention group, 50% of the control group; $P = .015$).⁸⁹ Among those who were uncertain at baseline or who planned to start with HD, 64% of the intervention group and 17% of the control group ($P = .01$) planned to start self-care dialysis at the end of the intervention period. Participation in the intervention group was associated with increased odds of choosing self-care (OR 10.2 [95% CI 2.0, 50.3], $P = .004$).⁸⁹ Of the 12 patients who started dialysis during a mean follow-up of 339 days, 2 patients died and 2 of 3 intervention group (4 of 7 control group) patients started with self-care dialysis.⁸⁹ Additional analyses identified patient-reported perceived advantages of self-care dialysis.⁹⁰ The advantages were categorized as “freedom,” “lifestyle,” and “control.” Freedom and lifestyle were significantly associated with intended choice of self-care dialysis (OR 9.1 [95% CI 2.0, 41.3], $P = .004$ for freedom; OR 7.0 [95% CI 1.6, 29.7], $P = .008$ for lifestyle). The perception of no advantage of self-care dialysis was associated with reduced odds of selecting that modality (OR 0.06 [95% CI 0.01, 0.24], $P < .001$). In the intervention group (but not the control group) there was an increase in the percentage identifying freedom and control as advantages and a decrease in the percentage reporting no advantage.⁹⁰ An earlier report of a cross-sectional survey of patients attending a progressive renal insufficiency clinic (active promotion of self-care dialysis) categorized barriers to self-care as knowledge, attitudes, and skills.⁹¹ For knowledge, lack of explanation of self-care and lack of understanding were the most frequently identified barriers. In the attitudes category, fear of social isolation, concerns about being unsupervised, lack of self-efficacy in performing self-care, and fear of substandard care were identified. Needle phobia, lack of space at home, and visual impairment were cited.

A study from Austria compared patients who voluntarily chose to attend a 2-day pre-dialysis education program to a standard care group.⁹² Of 70 patients from the education group who progressed to dialysis during the study period, 32 (46%) chose HD and 38 (54%) chose PD. Of 157 standard care patients who progressed to dialysis, 113 (72%) chose HD and 44 (28%) chose PD. The odds ratio for choosing PD following participation in the education program was 3.35 (95% CI 1.82, 6.14).

One US study compared a treatment options program (TOPs) to standard information in a non-randomized trial.⁹³ One analysis included 30,217 incident patients, 20,057 of whom attended TOPs. A second analysis included 2,800 matched pairs (TOPs or standard education matched on age, gender, race, diabetes, and geographic area). Of the 20,057 TOPs attendees, 27% chose in-center HD, 24% chose home-based HD, 13% chose transplant, 0.2% chose no therapy, and 35% did not make a choice. Follow-up data were available for 5,565. Twenty-five percent started a home-based dialysis therapy (predominantly PD). Among patients who did not attend TOPs, 3% started a home-based dialysis therapy. It was noted that TOPs attendees were younger, more

likely white, and had fewer comorbid conditions. Of the 2,800 matched pairs, 24% of TOPs attendees and 4% of non-attendees chose PD (OR 7.73 [95% CI 3.26, 18.32]).

Participants in the CHOICE study were asked to complete a survey about satisfaction with dialysis care.⁹⁴ The analysis focused on patients from centers that offered both HD and PD. PD patients were more likely to rate as “excellent” the amount of information they received on choosing HD or PD (relative probability 2.65 [95% CI 2.21, 3.02]) and the amount of dialysis information (relative probability 2.07 [95% CI 1.78, 2.32]).

A recent retrospective cohort study from Canada identified reasons for not choosing PD after expressing an intention to initiate PD.⁹⁵ PD was actually initiated by 59% of those who expressed an intention to initiate PD. Patient reasons included preference for hospital-based treatment (37%) and lack of space in home (1.6%). Medical reasons included an acute start to dialysis (37%), abdominal surgeries (8%), hernia (3%), and obesity (2%).

A prospective cohort study from France reported outcomes from patients who expressed a preference for PD or HD.⁹⁶ HHD was not an option in the region of France where the study took place. Of 177 patients who received information on dialysis modalities prior to starting dialysis, 82 (46%) preferred PD. Forty-five of these patients went to RRT with 21 (47%) receiving PD. Of 49 patients preferring HD, 33 went to RRT with 32 (97%) receiving HD. Of 34 patients who were undecided, 11 went to RRT with 9 (82%) receiving HD. Twelve patients were reluctant to undergo dialysis. Three went to RRT with all receiving HD.

A separate group of 51 patients in this study had been on HD for less than one month at the time of the information sessions having received no formal information prior to starting on HD.⁹⁶ Fourteen of these patients (27%) preferred PD and, of 12 patients alive at 3 months, 4 (33%) had switched to PD. Twenty-six preferred to stay with HD and 25 were alive at 3 months. Eleven were undecided but all stayed with HD and were alive at 3 months. Reasons for preferring PD included ability to receive treatment at home, autonomy, comfort to travel, and employment compatibility. Reasons for preferring HD included treatment in a medical facility, autonomy, socioeconomic criteria, socializing/security, and reluctance to have an intra-abdominal catheter. Mismatches between preference and treatment were noted only for 29 patients who expressed a preference for PD. The mismatches were due to medical causes (predominantly abdominal contraindications) in 48% and other causes (including medical center transfer, adverse opinion of family or employer, and change of opinion) in 52%.

A survey of patients in the UK who had already made a modality choice following an education program reported differences between HD (n=82) and PD (n=24) patients.⁹⁷ The PD patients were younger than the HD patients, had lower comorbidity scores, and were more likely married and employed or in school, and less likely living alone. Patients who chose PD identified the following factors as significantly more important than did the patients who chose HD: receiving written information on the modality, the modality fitting with lifestyle, and family/home/work circumstances. Patients who chose HD scored past medical history significantly more important than did the patients choosing PD.

A study from Italy looked at time of referral relative to start of dialysis (≤ 3 month or > 3 months) and, for patients referred more than 3 months before dialysis, the effects of a unstructured pre-dialysis clinic versus a formal multidisciplinary pre-dialysis care program.⁹⁸

Patients at the study centers were encouraged to consider PD if they had no major clinical or psychological contraindications or personal unwillingness. Participation in modality selection was less common for patients referred 3 months or less before dialysis (63% vs 78%, $P = .015$) as was choice of PD (30% vs 48%, $P = .006$). There was no difference in participation in selection or choice of PD between patients receiving standard pre-dialysis care or multidisciplinary care. More patients receiving multidisciplinary pre-dialysis care had a planned dialysis start compared to those receiving standard care (91% vs 39%, $P < .001$) and choice of PD was higher in those with a planned start (56% vs 24%, $P < .001$).

A before and after study from the US evaluated the effect of a comprehensive infrastructure change in dialysis care.⁹⁹ All patients were invited to visit both HD and PD unit, received information booklets and films, and were encouraged to discuss dialysis with current patients. The intervention included nephrologist placement of PD catheters, identification and training of family members or nursing home staff, increased social support, early ESRD education, and provision of in-center intermittent PD for selected patients. Individual elements of the program were evaluated. There were significant increases in the number of PD patients following training of nursing home staff, training of family members and providing support, early ESRD education, improving home conditions, and nephrologist catheter placement. The percent of patients choosing PD increased from 19% to 76% ($P = .001$) and the percent of dialysis patients at the facility who were on PD increased from 16% to 40%.

In the study from Spain (reported above), patients who received PD by their choice had lower mortality than those forced to accept PD for medical reasons (3.5% vs 20.4%, $P < .001$).⁷⁶ The peritonitis rate was also lower (0.46 vs 0.82 per year at risk, $P < .05$).

Findings from an interview with 188 HD and PD patients who began dialysis at least 3 months prior found no significant difference in “depressed mood” (Beck Depression Index score > 9) but higher quality of life (General Health Perceptions score ≥ 70) in HD patients compared to PD patients.¹⁰⁰ There were no differences across modalities in patients reporting negative effects of their current dialysis modality for aspects of daily life (ability to perform daily tasks, ability to control your life, relationships, getting needed sleep, anxiety, or interest in sex). There was a difference in feelings about how you look with a higher percentage of CCPD patients reporting a negative effect compared to either CAPD patients or HD patients. Using a time trade-off format, approximately 38% of HD patients would switch to CAPD if it increased survival time by 20%; approximately 66% would switch for a 100% increase. Similar values were reported for CAPD and CCPD patients in regard to switching to HD.

Choice of PD or HD was reported for patients from the NECOSAD cohort.⁸⁴ Of 1,346, 864 (64%) made their own choice (52% HD, 48% PD). The choice of HD was significantly more likely for age groups 55 to 65 years, 65 to 70 years, and 70 years and older compared to 18 to 40 years. There was no significant difference for patients 40 to 55 compared to 18 to 40 years. Females and patients living alone were significantly more likely to choose HD while patients with greater serum albumin and who received pre-dialysis care were more likely to choose PD. Technique survival at 12 months for patients who chose their dialysis modality was 93% for HD patients and 74% for PD patients. At 24 months, the corresponding values were 91% and 62%.

Two studies from the US looked at factors associated with choice of PD as initial dialysis modality.^{101,102} In a study of 2,344 incident HD and 670 incident PD patients, black or “other”

race (vs white), lower socioeconomic status, and older age (65 to 74 years vs 45 to 54 years) were associated with decreased likelihood of selecting PD. Gender, renal diagnosis, and timing of referral were not significant predictors.¹⁰¹ In an earlier study of over 10,000 patients, African American race (vs white), age 20 or older (versus under 20 years), moderately or severely impaired functional status (vs normal), 12 or fewer years of education, and not being a home owner were associated with decreased choice of PD.¹⁰² Employment or student status and living with family members were associated with increased use of PD although in a multivariable analysis, the association was not statistically significant. Gender was also not a significant predictor of choice.

Technique Survival

Fourteen studies presented data on factors associated with technique survival for PD.^{78,103-115} One additional study reported change in technique survival over time comparing data from patients initiating PD between 1995 and 2000 with data from patients initiating PD from 2006 and 2009.¹¹⁶ Additional study information is presented in Appendix C, Table 6.

Eight studies were from the US,^{78,103,106,108-110,113,115} 2 from the Netherlands,^{107,114} 2 from Canada,^{111,116} and one each from Australia/New Zealand,¹¹² France,¹⁰⁴ and Ireland.¹⁰⁵ Sample sizes ranged from 118¹¹⁴ to 41,197.¹¹³ There were 7 registry studies,^{78,103,104,111-113,116} 4 reports from prospective clinical cohort studies,^{107,109,110,114} and 4 retrospective studies, each from a single center.^{105,106,108,115} Follow-up times ranged from 1 to 9 years. Across the studies, the patient populations were similar with the exception of one study that enrolled only patients 75 years of age or older. In the remaining studies, mean ages ranged from 50 to 68 years and 49% to 65% were male.

Technique failure was defined in most studies as a switch from PD to HD. Four studies identified switches of 30 days or more^{103,109,110,112} while others included switches of 60^{104,113} or 90 days or more.^{111,116} Five studies did not specify a duration of HD.^{78,105,106,114,115} One study defined failure as a permanent switch to HD or death on PD.¹⁰⁷ Another study assessed catheter failure (removal of a dysfunctional PD catheter).¹⁰⁸

Factors associated with technique failure are summarized on Table 5; more detailed information can be found in Appendix C, Table 6. Increased BMI or categorization as obese was associated with higher rates of technique failure in 3 of 4 studies evaluating that factor.^{109,112,113} Increased systolic blood pressure (2 studies reporting)^{103,114} and catheter problems (2 of 3 studies reporting)^{108,112} were also associated with higher rates of technique failure. African-American race was associated with increased technique failure in 3 of 5 studies that reported results by race^{103,109,115}; a sixth study observed increased technique failure in the indigenous population of Australia/New Zealand.¹¹² Findings were mixed for presence of diabetes, age, gender, PD type, and geographical distance to the clinic/nephrologist. A small US study found no difference in technique failure based on distance¹⁰⁹ while a large Canadian study found lower technique failure with increased geographical distance from the nephrologist.¹¹¹ The authors noted a slightly higher mortality risk among remote-living PD patients. One study reported higher technique failure in patients with cardiovascular disease and in patients with lower eGFR.¹⁰⁷ Patients from larger dialysis centers had lower rates of technique failure in 2 US studies.^{78,110} Need for assisted PD was associated with decreased technique failure in a large study from France¹⁰⁴ but not in a smaller study from Ireland.¹⁰⁵

The temporal study found a lower adjusted risk of technique failure among patients initiating PD between 2001 and 2005 compared to the 1995 to 2000 group (HR 0.89 [95% CI 0.82, 0.98]).¹¹⁶ There was no significant difference between the 2006 to 2009 group and the 1995 to 2000 group (HR 0.95 [95% CI 0.85, 1.06]). Among patients older than 65 years, there was a lower risk of technique failure for both of the more contemporary groups compared to the 1995 to 2000 group.

Home Hemodialysis

Selection

Not all patient homes are suitable for HHD. An observational study from the UK reported on findings after visits to the homes of 249 patients who were medically suitable for HHD.¹¹⁷ One-third of the homes did not meet the Decent Home Standards. Hazards to health/well-being included overcrowding (57%), dampness/mold growth (33%), inadequate facilities for sanitation and drainage (17%), risk of structural collapse (10%), inadequate domestic hygiene, pests, and refuse (8%), inadequate facilities for storing and preparing food (8%), and inadequate supply of uncontaminated water (3%). Due to spatial, health, and safety concerns, 30% of the homes were not suitable for either HD or PD.

A Canadian study of 236 patients initiating HHD or PD looked at differences between HHD and PD patients.¹¹⁸ HHD patients tended to be male (70% vs 50%, $P = .05$), were younger (46 vs 62 years, $P < .001$), were less likely to have diabetes (24% vs 45%, $P = .003$), and had a longer delay between first renal replacement therapy and the start of HHD (4.8 years vs 0.34 years, $P = .002$).

Another Canadian study compared HHD patients ($n=15$) to PD ($n=79$) and in-center HD ($n=59$) patients.¹¹⁹ HHD patients were younger, had a lower BMI, and were more likely working than either PD or in-center HD patients (all $P < .05$). HHD patients were more likely English-speaking than HD patients. There were no differences in eGFR or comorbidity index values at the start of dialysis. Patients reported not choosing HHD because of disinterest (25%), lack of social support (25%), inadequate space (5%), communication issues (5%), and inability to perform own dialysis (3%).

A third study from Canada surveyed 66 nocturnal HHD patients and 199 HD patients with no contraindications or other factors limiting ability for HHD.¹²⁰ The surveys were completed by 85% of the HHD patients and 77% of the HD patients. The nocturnal HHD patients were significantly younger, less likely to have diabetes, and had a higher physical quality of life (SF-12). There was no difference in gender, the mental component of the SF-12, perceived ability for self-care, perceived social support, or anxiety. HHD patients were more likely to be comfortable with self-cannulation, believe they will receive as good care as with HD, believe they can properly perform nocturnal HHD, and be less fearful of a catastrophic event.

Table 5. Overview of Factors Evaluated for Technique Failure (Switch from PD to In-center HD)

Study (N) Country	African American/ Race	↑ BMI or Obesity	Diabetes	↑Systolic BP	CVD	↓GFR	↑ Age	Gender	Catheter problems	CAPD (vs APD)	Other
Shen 2013 ¹⁰³ (1587) USA	↑			↑				↓ female			↑Disabled ↑On Medicare ↔Others
Lobbedez 2012 ¹⁰⁴ (9882) France			↔				↓	↑			↓Assisted PD (vs self-care) ↑HD before PD
Smyth 2012 ¹⁰⁵ (148) Ireland							↔		↔		↔Etiology of ESRD ↔Catheter method ↔Comorbidities ↔Assisted PD
Taveras 2012 ¹⁰⁶ (235) USA	↔						↑	↔			
Kolesnyk 2010 ¹⁰⁷ (709) Netherlands			↑		↑	↑	↑			↔	
Singh 2010 ¹⁰⁸ (315) USA	↔	↔	↔				↔	↔	↑		
Jaar 2009 ¹⁰⁹ (262) USA	↑	↑	↔				↔				↔Geographical distance to clinic ↔Others
Plantinga 2009 ¹¹⁰ (236) USA											↓Clinic with > 50 PD patients
Tonelli 2007 ¹¹¹ (26,775) Canada											↓Geographical distance to nephrologist
Mujais 2006 ⁷⁸ (40,869) USA			↑				↑			↑	
McDonald 2003 ¹¹² (9440) ANZ	↑ Indigenous	↑					↔		↑		
Snyder 2003 ¹¹³ (41,197) USA		↑									
Jager 1999 ¹¹⁴ (118) Netherlands				↑							↓Urine volume ≥1000 mL/24hr ↓Peritoneal ultrafiltration
Korbet 1999 ¹¹⁵ (233) USA	↑										

ANZ = Australia/New Zealand; APD = ambulatory automated peritoneal dialysis; BMI = body mass index; BP = blood pressure; CAPD = continuous ambulatory peritoneal dialysis; CVD = cardiovascular disease; eGFR = estimated glomerular filtration rate; ESRD = end stage renal disease; PD = peritoneal dialysis

↑ = Significantly associated with higher rates of technique failure; ↔ = Not associated with higher rates of technique failure; ↓ = Significantly associated with lower rates of technique failure

Technique Survival (Appendix C, Table 6)

A prospective cohort study from the UK identified 142 HHD survivors and 24 who switched from HHD.¹²¹ In a multivariate analysis, only comorbid diabetes was a significant predictor of technique failure (HR 3.96 [95%CI 1.66, 9.49]). Patient-reported reasons for switching modalities (provided by 11 of 18 patients who were alive at the end of the study period) included family dynamics (20%), lack of carer support (17%), lack of confidence with procedure (15%), interference with home life (15%), and medical issues including access (12%).

A retrospective study from Canada included data from 177 patients (145 successful, 32 failures) who initiated training for nocturnal HHD.¹²² The study site had a “home-first” policy whereby only patients with absolute contraindications were not invited to trial for HHD. In a multivariable analysis, ESRD due to diabetes and renting current residence were significantly associated with failure. The most common reasons for failure associated with training for HHD included inappropriate housing, deteriorating medical status, inability to cope with burden of HHD, non-adherence, and test failure. The most common reasons for technique failure included deteriorating medical status, inability to cope with burden of HHD, change in residence, inadequate family support, caregiver anxiety, and inability to perform cannulation.

A second report from the same study site looked at differences in outcomes between patients characterized as dependent (partially or totally n=47) or independent (n=152) based on need for assistance with nocturnal HHD.¹²³ The adjusted hazard ratio for a composite outcome of time to all-cause hospitalization, technique failure, or death was not significant (HR 1.25 [95% CI 0.76, 2.04]). The need for back-up dialysis runs at an in-center or training facility did not differ between dependent and independent patients but dependent patients did require more home visits by nurses (RR 2.03 [95% CI 1.39, 2.97]).

An analysis of data from the CAN-SLEEP Collaborative Group cohort study also included only nocturnal HHD patients.¹²⁴ Most patients (74%) were able to perform HHD independently. Among 247 patients, there were 10 technique failures. The only significant predictor of failure was age with an HR of 1.09 (95% CI 1.03, 1.16) for each 1 year increase in age. Using a composite outcome of death or technique failure (36 events), age and diabetes were significant predictors.

A prospective cohort study from Canada included all patients who began training for HHD.¹²⁵ Patients had experienced a mean of 30 months of dialysis before entering the program. During follow-up of up to 3 years, 37 patients dropped out of the program including 13 who received transplants, 14 who died, 2 with inadequate social support, 2 with medical reasons, 2 with inadequate dialysis, 1 who moved, 1 who withdrew from dialysis, and 2 with unspecified reasons. No significant predictors of technique survival were identified.

Risk of Bias for Key Question 3

We did not assess the risk of bias of individual registry studies. Registry studies are typically considered high risk of bias due to issues with selection bias and inability to assess and include all potential confounders in analyses. Other studies pertaining to Key Question 3 were one high risk of bias RCT and 2 CCTS (both moderate risk of bias), 5 reports of clinical cohort studies (4 rated high risk of bias and one moderate risk of bias), 24 cohort studies (2 low, 8 moderate, and

14 high risk of bias), and 9 cross-sectional studies (one low, one moderate, and 7 high risk of bias).

KEY QUESTION 4. In the published literature, what are the costs of home hemodialysis or peritoneal dialysis compared to in-center hemodialysis?

Summary of Findings

Fifteen studies (2 from the US) reported cost outcomes. Cost analyses have typically reported lower costs for HHD and PD compared to in-center HD. However, what costs are considered in the analyses and factors that can influence costs (*eg*, failure rates, patient age, and comorbidity) vary across studies.

Costs of Home Hemodialysis versus In-Center HD (Appendix C, Table 7)

Cost-utility analysis of data from the randomized Alberta nocturnal HHD study found frequent nocturnal HHD led to incremental cost savings of \$6700 Canadian dollars (US\$5872 in 2014) and an additional 0.38 QALYs compared to conventional HD but the savings and quality of life improvements varied by technique failure rate, training time, and dialysis modalities from which patients are drawn.¹²⁶ The study was also limited by the small sample size and short study duration. Results from a modeling study, based on data from Australia, Canada, and the United Kingdom, found costs of conventional HHD and frequent HHD were similar to costs of in-center HD in the first year but over time conventional HHD and frequent HHD could be less costly than in-center HD depending on the frequency of dialysis.¹²⁷ The model predicted that conventional HHD would save payers between \$7612 (US\$6668 in 2014) and \$12,403 (US\$10,865) over the first year of conventional in-center HD. An Australian study, based on new ESRD patients in the ANZDATA Registry from 2005 to 2010, estimated that switching patients from hospital HD to HHD would produce a net saving of \$47 million Australian dollars by 2010 (US\$40 million in 2014), suggesting changes in clinical practice would not only reduce costs but also improve patient quality of life.¹²⁸ However, the analysis did not incorporate indirect costs such as lost earnings and productivity and direct out-of-pocket costs to patients and their care givers. These results were supported by an earlier cost-effectiveness modeling study based on data from a systematic review.¹²⁹ A Finnish study reported no significant differences in the total costs between HHD and satellite HD and costs for both modalities were clearly less than those reported for hospital HD in other studies.¹³⁰ The results were limited by the younger age and shorter dialysis duration compared to general dialysis patients, limiting the application of the results to older and frailer patient populations. A Canadian study that analyzed patients' conventional HD costs during the 12 months before study entry found reduced costs and improved quality of life after switching to quotidian HHD, but the study was very small and under-powered to detect statistically significant differences in costs.¹³¹ Older analyses have reported that reductions in costs associated with HHD compared to conventional HD are linked to a lesser need for nursing and other personnel and the exclusion of overhead costs of dialysis center or unit management.^{132,133}

Costs of Peritoneal Hemodialysis (PD) versus In-Center HD (Appendix C, Table 7)

A recent Canadian study, based on data from the Alberta renal programs, found PD patients and patients who transitioned from HD to PD had significantly lower total health care costs at one and 3 years. Patients who had PD technique failure had costs similar to, not in excess of, HD patients at 3 years, supporting an economic rationale for a PD-first policy in all eligible patients.¹³⁴ A study from Spain reported costs related to dialysis access at 1 year from the time of

first dialysis.¹³⁵ There were significantly more access-related interventions in the HD groups (tunneled cuffed catheter or arteriovenous fistula) than the PD group. Access-related costs were significantly higher for the tunneled cuffed catheter HD group (€4208, US\$4467 in 2015) compared to the arteriovenous fistula HD group (€1555, US\$1651) or PD group (€1171, US\$1244). A retrospective cohort study based on a US health insurance database reported that PD patients had significantly lower total healthcare costs during the year following initiation of dialysis, largely a result of higher emergency department visits and hospitalizations in the HD group.¹³⁶ Median total per-patient healthcare costs over the 12-month follow-up period for the PD and HD patients were \$129,997 and \$173,507, respectively. Findings from a UK study also reported lower costs associated with PD compared to in-center HD.¹³⁷ Costs associated with PD were mainly the costs of solutions and management of anemia while costs associated with HD were mainly due to disposables, nursing, and the overheads associated with running the dialysis unit. Other analyses also estimated that PD was the more economically advantageous dialysis modality¹³⁸⁻¹⁴⁰ and a longer time on PD better sustained this economic advantage even after a switch to conventional HD.¹³⁹ Several of these PD cost analysis studies were limited by basing the analyses from the health-care provider perspective or including direct costs only and not incorporating indirect costs such as lost earnings and productivity.^{134,138,139}

SUMMARY AND DISCUSSION

Key Findings and Strength of Evidence

- We found few randomized or controlled clinical trials or prospective clinical cohort studies comparing home-based and in-center kidney dialysis. Available clinical trials were small in size and had short follow-up durations.
- Most of the data on mortality is from registry studies. Results from these studies should be interpreted with caution due to likely residual confounding and selection bias.
- Home hemodialysis (HHD) versus in-center HD:
 - We found low strength of evidence (findings from registry studies) that HHD is associated with improved overall survival compared to in-center HD (Table 6). There were few studies of variations of HHD (including longer duration or more frequent sessions).
 - There is evidence from generally low-quality studies to suggest no difference in cardiovascular mortality, no difference or improved quality of life with HHD, no difference in access survival, no difference in transplantation rate, and no difference in all-cause hospitalization rate. In 2 studies reporting, a higher percentage of HHD patients switched dialysis modalities over follow-up periods of up to 4 years.
- Peritoneal dialysis (PD) versus in-center HD:
 - We found low strength of evidence (findings from registry studies) that there is no difference in overall mortality between PD to in-center HD (Table 6). However, most studies reporting outcomes over time noted an early survival advantage for PD patients with no difference after 2 to 3 years of treatment.
 - There were inconsistent findings for quality of life outcomes with studies reporting no differences or higher scores on some elements of quality of life in PD or in-center HD patients. With limited reporting, results were mixed for cardiovascular outcomes, adverse events, transplantation, and hospitalization. Over follow-up periods of 2 to 7 years, higher percentages of PD patients switched dialysis modalities.
- Only 2 studies compared HHD and PD with mixed results for mortality. Other outcomes were not reported.
- Factors associated with increased selection of home-based dialysis:
 - Facility factors: larger facility, more years of Medicare certification, providing care for more employed patients or patients in the 18 to 54 year age range, earlier initiation of pre-dialysis care, increased patient/family education;
 - Patient factors: well-informed about choices, patient preference (more autonomy, more flexible schedule, and less travel to dialysis), family/caregiver support;

- Provider factors: team approach (physician, nurse, social worker) to determining patient eligibility (medical and psychosocial).
- Factors associated with decreased selection of home-based dialysis:
 - Facility factors: location in more rural area, location in high density zip code area, availability of an evening shift, higher percentage of black patients;
 - Patient factors: lack of knowledge, living alone, lack of space in the home, inability to perform PD in the place of residence, fear of social isolation, fear of inability to perform PD, and preference for medical supervision.
- Factors associated with technique failure:
 - Facility factors: lower technique failure if receiving care from larger dialysis facilities;
 - Patient factors: higher technique failure if lack of caregiver support, caregiver anxiety, medical issues (including diabetes or psychosocial problems), treatment interferes with home life, African-American race (vs white), HD before PD;
 - Provider factors: none identified.
- Costs are lower with HHD and PD compared to in-center HD but costs considered in the analyses and factors that can influence costs (failure rates, patient comorbidity) varied across studies.

Table 6. Strength of Evidence for Mortality Outcome

Outcome (studies reporting)	Results	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Overall Mortality HHD vs HD (6 registry studies)	4 of 6 studies reported decreased overall mortality with HHD	high	consistent	direct	precise	low
Overall Mortality PD vs HD (19 registry studies)	4 studies reported decreased mortality with PD 6 studies reported increased mortality with PD 9 studies reported no difference in mortality	high	inconsistent	direct	imprecise	low

HHD = home hemodialysis; HD = in-center hemodialysis; PD = peritoneal dialysis

This evidence report summarizes literature on the comparative effectiveness and harms of home-based versus in-center dialysis. Home-based dialysis is a potentially effective option of considerable interest to Veterans and could permit VA to expand internal dialysis capacity. However, it is not well known if this is feasible within the Veteran population, due to in part to a greater prevalence of patients of older age and a greater number of comorbidities in the VA system. None of the included studies were conducted at VA medical centers.

Data on clinical outcomes come predominately from large registry studies, not randomized controlled trials. While authors attempted to control for confounding, significant residual confounding from both measured and unmeasured variables likely exists. Patients who undergo home dialysis are generally different than those who undergo in-center dialysis. In the United States patients undergoing home dialysis are generally younger and healthier than those treated with in-center hemodialysis. Also, patients without insurance and those without pre-dialysis care who present emergently requiring dialysis are much more likely to be initiated on in-center hemodialysis. These differences in patient characteristics can be inferred by the greater rate of transplantation among patients undergoing peritoneal dialysis compared to those undergoing in-center hemodialysis, which may then result in artificially increased death rates in PD groups in later periods of follow-up. Given these stark differences between patient populations it is difficult to compare outcomes across these populations, irrespective of the type of statistical technique employed.

DISCUSSION

Our findings are in agreement with earlier reviews and guidelines. A guideline from Caring for Australians with Renal Impairment (CARI) concluded that no clinical care recommendations could be made that would be based on Level I or Level II evidence.¹⁴¹ The authors offered clinical care suggestions based on Level III or Level IV evidence including that PD may provide equivalent or better survival in the first few years, the HD may offer better long-term survival, and that timely transfer from PD to HD may improve survival. Based on opinion, it was suggested that survival be considered in the context of life quality as perceived by the patient when selecting a dialysis modality.

Other reviews have identified health care system, provider, and patient factors that are important in selection of home-based dialysis. Golper et al summarized barriers to home dialysis as educational issues (patient education; physician education, training, and experience; and dialysis staff education and experiences), governmental issues (reimbursement, financial support for home caregivers, accreditation and certification, required home visits, and regulatory policies that limit access to innovative equipment and solutions), and business practices and philosophies of dialysis providers (availability and delivery of equipment and supplies, business conflicts with patient care, laboratory and pharmacy services availability, space for training and clinic visits, and staffing).¹⁴²

A second review focused on establishing a successful HHD program.¹⁴³ Patient education (including training on and practice with the equipment), physician training, nurse training (to prepare them to train patients), and staff support for patients and caregivers are essential. The creation of centralized training facilities (combining resources from multiple practices) and the use of continuous quality improvement cycles to monitor and modify treatment protocols were also suggested. The authors provided information on best demonstrated practices related to choice of dialysis equipment, dialysis schedule, vascular access, and remote monitoring; design of the patient training program; home assessment; post-training expectations; and patient or family burnout.

In a 2006 publication, patient preference (in the absence of a strong indications for or against a particular modality), medical factors, social issues, and non-medical issues (including financial reimbursement, late referral to a nephrologist, and nephrologist attitudes, opinions, educational

deficits, and biases) were described as contributing factors in selection of a dialysis modality.¹⁴⁴ The authors proposed an integrated care approach with early referral, aggressive management of CKD, promotion of living donor transplantation as first-line treatment for ESRD, unbiased education about all dialysis modalities, encouragement for suitable patients to select a home-based modality as initial therapy, and recognition that treatment modalities may be complementary rather than competing in providing optimal outcomes.

A 2013 meta-analysis focused on the modality decision-making process.¹⁴⁵ The analysis included 16 qualitative studies of adults (total n=410) with CKD. All but one of the studies was conducted in North America, Europe, or Australia/New Zealand. Across the studies, 3 themes emerged. First, patients perceived they had little true choice about commencing dialysis or dialysis modality – dialysis was necessary for survival. Often the choice was made in a short time frame by family or physician due to unforeseen medical situations. Second, minimizing intrusiveness was important. Patients believed that dialysis should allow for a good quality of life in addition to prolonging life. Third, knowledge (for both the patient and family members) and social support were important. The authors concluded that there is a need for CKD patients and their caregivers to participate in planned and timely discussions about dialysis modalities, including home-based care. Healthcare professionals should prepare patients and families for decision-making and provide information about different dialysis modalities and potential effects on quality of life, values, autonomy, and sense of self.

Overall treatment satisfaction with PD was the focus of another 2013 systematic review.¹⁴⁶ Included were 39 qualitative studies of the experiences, beliefs, and attitudes about PD from adults on long-term PD. Sample sizes in the individual studies ranged from 2 to 45 with 4 studies not reporting sample size. All but 4 studies were from North America, Europe, or Australia/New Zealand. Seven major themes were identified and these were subsequently organized into a thematic schema. “Resilience and confidence” (determination, overcoming anxieties associated with diagnosis of ESRD) and positive “support structure” (strong family relationship, peer support, professional dedication) contributed to a positive adjustment to PD. A positive adjustment resulted in perceptions of “control” (bodily awareness, independence and self-efficacy, information seeking) and “freedom” (treatment integration, social functioning, ability to travel). “Overwhelming responsibility” (disruptive intrusion, family burden, onerous treatment regimen) and negative “support structure” (social abandonment, desire for holistic care) contributed to a negative adjustment to PD which resulted in perceptions of a “sick identity” (damage to self-esteem, invisible suffering) and “disablement” (physical incapacitation, social loss and devaluation). It was concluded that while PD can have advantages for patients, strategies to strengthen social support and promote confidence are necessary for achieving positive adjustment and treatment satisfaction.

There is limited data on caregiver burden associated with dialysis and whether HHD is more stressful for caregivers. In a study from Italy, where HHD is rare, patients and caregivers were interviewed.¹⁴⁷ The 22 adult patients were currently receiving in-center HD; some were potentially eligible for HHD. The 20 caregivers, identified by the patients, were adults who provided care or support on a regular basis. The participants were selected to represent both genders and a range of ages, durations of dialysis, years of caregiving, and relationships to patients. Positive and negative themes were identified. On the positive side, flexibility and freedom, comfort in familiar surroundings, and altruistic motivation (setting an example for others) emerged. Negative themes included disrupted sense of normality, family burden, housing

constraints, concern over healthcare by “amateurs,” and isolation from peer support. Specifically, both patients and caregivers thought that HHD would be an “overwhelming responsibility” for a caregiver. Caregiving would require “significant personal sacrifices” that would impact work and social lives. Caregivers were concerned about seeing the patient “suffer” while undergoing dialysis, their ability to assist the patient with treatment and technical problems or complications that might arise, and their ability to manage “medical responsibilities.” Caregivers also reported that they perceived patients were content with their in-center care and that they benefited from peer support. The authors identified education, providing support for caregivers and family members, minimizing the intrusiveness of HHD, maintaining patient access to medical and technical support, minimizing social isolation, and promoting self-efficacy as ways to increase acceptability and selection of HHD. Suri et al reported results from the Frequent Hemodialysis Network Trials.¹⁴⁸ Patients in the Daily Trial completed dialysis in-center either 3 or 6 times per week while those in the Nocturnal Trial completed dialysis at home with either conventional dialysis 3 times per week or nocturnal dialysis 6 times per week. The analysis included patients who reported having an unpaid caregiver. Scores on a perceived burden scale at 4 and 12 months were lower than baseline (indicating less perceived caregiver burden) for the Daily Trial participants regardless of dialysis schedule and for the conventional home dialysis patients. Scores increased from baseline (indicating greater perceived caregiver burden) at 4 and 12 months for the nocturnal home dialysis patients. The authors suggested that the findings may play a role in the choice of frequent home nocturnal dialysis.

LIMITATIONS

Two studies found no difference in transplantation rates between HHD and HD. This finding may be a result of the length of time before a donor kidney becomes available. Studies with short follow-up could demonstrate no difference.

If there is an advantage of HHD over HD, it may be related to the different frequencies of dialysis or treatment times per session that are possible with HHD.²²

Quality of life outcomes should be interpreted with caution. Often the studies are comparing groups of patients with different amounts of time on dialysis (*eg*, quality of life assessed at 3 months in one group versus 15 months in the other group). Familiarity with and adjustment to dialysis and/or disease progression might be more important factors in reported quality of life than the dialysis modality. In addition, baseline characteristics (*eg*, age, comorbidities) of the patients in the treatment groups differ and might account for differences in reported quality of life. Finally, assessment of quality of life during an in-center HD session versus at home or during a routine office visit (no dialysis) may yield different quality of life scores. The use of generic versus disease specific assessment tools should also be considered.

Applicability of Findings to the VA Population

Twenty of the 32 registry studies were completed in the United States or Canada. Across all registry studies, mean ages ranged from 47 to 75 years and between 50% and 67% of included patients were male. There were few exclusion criteria, suggesting that the patients were representative of the ESRD population. However, the cohort years for all but 7 of the registry studies were prior to 2008.

We found no compelling evidence that HHD and PD differ from in-center HD in survival, quality of life, hospitalizations, or costs. Differences, where they exist, could be due to unmeasured differences in patient populations and strong selection biases (by patients, caregivers, or providers). However, HHD and PD are commonly used as the dialysis method of choice in other countries. We also found some evidence that caregiver support was an important factor in identifying candidates likely suitable for HHD or PD.

RESEARCH GAPS/FUTURE RESEARCH

Despite the large number of studies included in this report considerable gaps exist. The comparative effectiveness of HHD or PD to in-center HD (including outcomes of mortality, hospitalizations, quality of life, patient satisfaction, and adverse events) and whether treatment choice and technique success vary by modality, patient, provider, or facility factors remains relatively unknown. This is predominately because considerable differences likely exist among individuals selected (or selecting) different treatment modalities. While difficult to undertake, a large randomized trial comparing different modalities would be useful. Other research needs would be to evaluate methods to understand barriers to and improve implementation of HHD or PD and provide individuals with sufficient skill building and caregiver support in attempts to maximize benefits. Of note HHD and PD are widely used as treatment options of choice in other developed countries.

CONCLUSIONS

Low-strength evidence suggests that home-based dialysis may provide similar health outcomes and at similar or lower costs for many patients compared to in-center hemodialysis. Therefore, home-based dialysis may be an acceptable and sometimes preferred alternative to in-center hemodialysis. Information is limited on factors important in addressing selection of and barriers to home-based dialysis and remains an area of important research and health policy.

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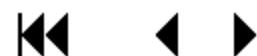
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