



## **KDIGO Controversies Conference on Supportive Care Objectives and Questions for Breakout Sessions**

### **Work Group 1: Symptom Assessment, Epidemiology and Management**

1. Epidemiology
  - a. What is the incidence / prevalence of symptoms in CKD/ESRD
    - i. Pruritus
    - ii. Fatigue, weakness/lethargy
    - iii. Pain
    - iv. GI symptoms: anorexia, nausea, vomiting, constipation, diarrhea
    - v. Sleep disturbances
    - vi. Restless leg syndrome
    - vii. Muscle cramps
    - viii. Dialysis headache
    - ix. Depression
    - x. Anxiety
    - xi. Sexual dysfunction
  - b. What are the consequences of the above symptoms and overall symptom burden on clinically relevant outcomes including physical function and quality of life?
  - c. What are the consequences of the above symptoms and overall symptom burden on resource utilization and healthcare costs?
2. Screening and diagnosis
  - a. What is the role of screening for the above symptoms?
  - b. What are the best screening tools for the above symptoms?
  - c. What are the best diagnostic tools for the above symptoms?



3. Treatment
  - a. What is the evidence for treatment of the above symptoms?
  - b. Are there clinical practice guidelines/policies in place to manage these symptoms?
    - i. Are these practice guidelines/policies supported by the available evidence?
  - c. Is the evidence sufficient to proceed with formal guideline development?
    - i. Given high prevalence and clinical consequences of symptoms and symptom burden can certain treatments be extrapolated from evidence from non-CKD/ESRD patients?
4. Are there special considerations for developing countries?
5. Knowledge gaps and research priorities
  - a. Pruritus
  - b. Fatigue, weakness/lethargy
  - c. Pain
  - d. GI symptoms: anorexia, nausea, vomiting, constipation, diarrhea
  - e. Sleep disturbances
  - f. Restless leg syndrome
  - g. Muscle cramps
  - h. Dialysis headache
  - i. Depression
  - j. Anxiety
  - k. Sexual dysfunction
6. Where do we go from here?
  - a. Final recommendations

## Work Group 2: Prognosis

1. What are the consequences of prognosis:
  - a. Effect on nephrology team
  - b. Effect on the healthcare system
  - c. Selection of candidates for RRT based on limited resources (AMA Criteria for scarce resources (Woody to provide document and summary))
  - d. Effect on patient and family - collaborate with the ACP workgroup
2. How and when is the tool used (ACP group)
3. What is the evidence for estimating prognosis?
4. Are there guidelines in:
  - a. USA
  - b. UK
  - c. Australia
5. Are these relevant to developing countries?
6. Ethical religious cultural aspects
7. Knowledge gaps and research priorities
  - a. Frailty
  - b. Dependent on transfers
  - c. Appetite
8. Existing tools: review existing tools and validation and relevance in different populations
  - a. Can we recommend existing tools in other countries?
  - b. Need for further validation and enhancement of tools
9. Discuss the use of large databases (Peter)
10. Do we recommend development of KDIGO guidelines for prognosis?

## Work Group 3: ACP and Shared Decision-Making

### **Subgroup 1: Advance Care Planning**

1. Can we describe a shared view of ACP and ADs?
2. Can we describe the legislative and regulatory framework within which ACP is practiced in the various regional jurisdictions?
3. What work has been done to identify and study the impact and interaction of the various regulatory, professional, cultural and economic barriers to AD and ACP in developed and developing countries?
4. What strategies have been employed to overcome these barriers? How successful have they been and what if any unintended consequences followed?
5. Update regulation regarding ADs in European countries (draft data is up to 2009; European colleagues may help with this)
6. Summarize what we know, what we don't know, and what we need to know regarding ACP/ADs (including its impact on not opting for dialysis)

### **Subgroup 2: Decision-making**

1. What are similarities and differences between preference sensitive decision-making components and processes in advanced kidney disease and other conditions?

The component parts of decision making will be the same (options, consequences, utilities, burdens, heuristic, systematic) but the weight given to them and/or the way they are combined and/or range of options during decision making may vary. For example, people with an illness rate equally all EQ-5D dimensions, people without an illness ranked 'life' dimensions as more important and rated more negatively the impact of illness on these components (Peeters, Vliet Vieland, Stiggelbout, 2012). It is possible that different types of illness and/or the stage of illness will impact on the weight given to these component parts, and how they are used to reach a decision. For example:

#### *Acute versus chronic conditions:*

- The treatment choice and consequences for acute conditions are made once, made/acted upon immediately, non-reversible, no impact on lifestyle, cures/ fixes health problem, possibility of side-effects.
- Treatment choices and consequences for chronic conditions are usually repeated, made/ acted upon when disease state changes, the choice made can be reversed, affects lifestyle, manages health problem, possibility of side-effects.

*Stable condition versus deterioration towards end of life:*

- The treatment choice and consequences for patients with stable conditions focus on adherence to treatment regimens and effective disease management, established pattern of engagement with health professionals, social service providers and family, adjustment and coping to condition to reach a lifestyle status quo.
- The treatment choice and consequences for patients with a condition deteriorating towards end of life may still include adherence to treatment regimens to manage disease as well as new treatments to manage additional problems, contact with more health and social care professionals, making more decisions about condition, social care, and lifestyle, adjustment and coping to further deterioration of health and its consequences.

It is possible, other factors may impact on the way decisions are made including: frailty/ function, age, cultural mores.

2. Summarize barriers to effective decision-making.

Barriers to effective decision making need to be thought of in terms of:

- Patient decision making (e.g. understanding, beliefs, emotions, motivation to act, skills and ability to carry out actions) and enabling informed decision making
- Professional decision making (e.g. awareness treatment and social care options, emotions, beliefs, etc ) and enabling accurate decision making
- The patient and professional interaction (e.g. opportunities to exchange relevant information) and enabling collaborate conversations.
- People with Systems-of-care (e.g. infrastructures to enable cross-disciplinary communication) and enabling integrated cross-service actions.

3. Discuss patient decision aids and other tools have been used to improved decision-making and ACP and EoLC in advanced kidney disease. What is the evidence re: feasibility, acceptability to patients and HCPs and effectiveness?

We found five interventions designed to support ACP/ EoL care decision making (Respecting Choices; Looking Ahead; Making Your Wishes Known; Planning location of care; Peace of Mind), three have been evaluated for their acceptability with patients and carers (Respecting Choices; Looking Ahead; Making Your Wishes Known). The studies found these aids could be integrated into practice, patients found them acceptable, they helped patients make decisions and patients wanted them earlier in their disease trajectory. These studies were carried out in North America only. Only one included patients with ESRD.

We found twelve interventions designed to support patients making treatment choices for ESRD (e.g. conservative care, dialysis, transplant; between transplant and dialysis; between dialysis types), five have been evaluated for their acceptability with patients (YoDDA; PREPARED; BOLDE; Shared Haemodialysis Care; iChoose Kidney), two are on-going (My kidneys, My choice; Ann Arbour Dialysis Decision Aid). All resources were acceptable to patients and helped them make their decisions. These studies were carried out in the UK, USA and Au.

4. What is the impact of a structured SDM approach to patient experience and outcomes in advanced kidney disease?

Kirchhoff et al (2012) found patients receiving the Respecting Choice, person-centred advance care planning intervention were more likely to withdraw from dialysis (37.7%), to be more certain of their choice, and less likely to want resuscitation, than those receiving usual care (17%).

Bekker et al (2013) found that YoDDA improved patients' experience of service delivery and the usefulness of information to increase understanding of kidney disease and dialysis, and enabled patients to make an informed choice preference more quickly than usual care. There are no data available on the impact of interventions on the experience and/or delivery of shared decision making and/or outcomes.

5. What studies of SDM in AKC are in progress?

- Boulware is carrying out an RCT of PREPARED (Baltimore, USA), a decision aid/ shared decision making intervention to support treatment choices for ESRD.
- Bekker (and YoDDA team) are completing a web-based evaluation of YoDDA (UK).
- Davison is evaluating the implementation of the Respecting Choices ACP programme (Canada).
- Patzer is developing the iChoose Kidney risk calculator (USA).
- Tentori (and Ann Arbout team) is developing a dialysis decision aid (USA).
- Fortnum is evaluating the 'My kidneys, my choice' shared decision making programme to support patients dialysis decisions (Au).
- Tomson (with Bekker and others) carried out a pilot study to evaluate the use of patient reported outcomes of shared decision making about treatment choices for ESRD, UK renal registry (2012-2013).
- Loiselle is evaluating the use of decision coaches in enabling shared decision making about treatments for ESRD (Canada).
- Roderick has carried out a review of palliative care/ conservative care practices by staff across the UK (2012-2013).

6. What additional studies of SDM in different settings are now required?

Although the indications are that well designed decision aids, delivered within services with a positive attitude towards shared decision making about ACP in ESRD, are acceptable to staff and patients and likely to impact on patient experience of care and health outcomes, the evidence base is weak. In addition, it seems likely that there will be variation by service providers to deliver systematically the range of practices required to support SDM alongside usual disease-management pathways. Finally, there is a paucity of evidence identifying the types of interventions that can best support SDM about ACP for ESRD, and the measures that will be most useful in evaluating their effectiveness, across a range of populations and health infrastructures. It might be useful to draw up

a typology of studies to help guide a coordinated program of research which would add data systematically to the evidence-base.

### Subgroup 3: Outcomes of ACP

1. What aspects of patient and caregiver experience have been subject to ACP interventions in kidney care and in other / mixed conditions?

The effect of an ACP intervention on a number of clinically-relevant patient-reported and objectively measured outcomes have been examined in randomized clinical trials. As discussed in our narrative above, there is great heterogeneity in the specific instruments and outcomes examined across 5 RCTs. This great heterogeneity precludes quantitative meta-analyses, and imposes challenges in comparing the effects of ACP across different outcomes. Specific domains examined in these RCTs are listed below:

1. Quality of Life (general and Health-related)
2. Depression and anxiety symptoms
3. Patient's sense of control and coherence
4. Patient and/or surrogate satisfaction – globally (patient and surrogate), and specifically the surrogate's satisfaction with patient's quality of death.
5. End-of life care and mode of death – e.g., - including location/setting of death (e.g., ICU vs. home vs. non-ICU hospital); incidence and timing of DNR orders; concordance of CPR and/or other EOL care provided with patient's/surrogate's wishes.
6. Concordance of patient's EOL wishes/preferences with those of patient's surrogate and/or physician.
7. General Knowledge of ACP (typically semi-quantitative scale 0 to 10).
8. Healthcare utilization (e.g., ICU days, hospitalization days, costs).
9. (For ESRD): Withdrawal of dialysis prior to death.

2. What impact of ACP on these parameters has been described?

1. Quality of Life - instruments including the Quality of Well-Being (QWB)
  - a. No effect of ACP observed.
2. Depressive and anxiety symptom burden
  - a. Significant improvement by ACP observed in 2 studies; no effect on anxiety in 1 small RCT.
3. Patient-reported sense of control and coherence:
  - a. No effect observed.
4. Patient and/or surrogate satisfaction:
  - a. Globally satisfaction with overall healthcare: No effect observed
  - b. Surrogate satisfaction with patient's quality of death: Increased satisfaction observed
5. End-of-life care and mode of death
  - a. Increase in % of deaths with EOL wishes known and followed in 1 RCT
  - b. No difference in concordance of CPR administered with patient's EOL wishes in another RCT (including the one trial with ESRD patients)
  - c. No increase in incidence and timing of DNR orders, or % with DNR orders in 2 other RCTs.
6. Concordance of patient's EOL wishes/preferences with those of patient's surrogate and/or physician:
  - a. Increased surrogate/patient concordance observed in 2 RCTs.

- b. Non-significant trend towards increased physician-patient concordance in another RCT.
  7. General knowledge of ACP:
    - a. Minimal effect observed in 1 RCT (statistically significant but of questionable clinical significance); no effect observed in 1 small RCT.
  8. Health care utilization:
    - a. No effect on hospitalizations/days in hospital, overall healthcare costs, ICU days, nor narcotic charges observed in 2 RCTs including largest RCT to date.
  9. Withdrawal of dialysis (in ESRD patients):
    - a. Large increase in withdrawal observed with ACP in 1 RCT.
3. What evidence is there for heterogeneity in the impact of ACP related to underlying condition(s), other patient / family characteristics and between different cultures?

There is *considerable heterogeneity* across studies in terms of:

1. Patient conditions – only 1 RCT has included a sizable sample of ESRD patients. Other RCTs have focused on cardiac surgery patients or those with HF. Most RCTs have not specified disease conditions, but rather focused on patients at high risk of mortality – e.g., those >80 years in acute care wards; adults with <50% 5-year life expectancy, or those with advanced stage chronic or acute organ dysfunction other than kidney failure.
  2. Interventions – several RCTs featured a much more labor-intensive facilitated patient-centered ACP intervention including disease-specific planning. Others have included lower-intensity generic ACP interventions with in-person or mailed advanced directive instructions. Only a single study specifically involved physician training in ACP.
  3. Role of surrogates- while some RCTs required an available designated patient surrogate for enrollment into the trial, other clinical trials did not have such a requirement.
  4. Training of ACP facilitators - where facilitators were utilized, this was described in the methods sections all RCT manuscripts, but the extent and detail of such training varied considerably across studies.
4. What are the key unanswered research questions regarding the value, efficacy and impact of ACP in advanced kidney disease? Are these studies amenable to formal systematic review and meta-analysis?
    1. Does disease-specific patient-centered ACP among patients with advanced non-dialysis CKD improve clinically relevant outcomes including QoL, quality of death, end-of-life care concordance, healthcare costs, and patient/family satisfaction?
    2. Which ACP interventions are feasible in healthcare systems with more limited resources?
    3. What is the effect of ACP in healthcare systems in which advanced care planning is utilized infrequently under local standards of care?
    4. Are there alternative study designs other than randomized parallel-group trials that can provide non-biased estimates of the effect of ACP in patients with advanced kidney disease?
      - Meta-analyses are challenging due to the wide heterogeneity of outcomes between different studies. Use of standardized outcome measures (e.g., validated QoL instruments) would facilitate quantitative systematic review of this intervention. Narrative (i.e. qualitative) systematic review may be more feasible.



5. What lessons can we glean from the current literature regarding acceptability, feasibility and required study design to deliver successful ACP studies in advanced kidney care?

1. Interventions to provide structured, facilitated ACP are effective at increasing the utilization of advanced directives.
2. The randomized trial is a feasible study design to test the effect of ACP in patients at high mortality risk, including those with ESRD.
3. There is insufficient data from clinical trials to identify those aspects of ACP most effective in ESRD patients.
4. Patient-centered ACP is feasible in ESRD and may have potentially beneficial effects on clinically relevant outcomes.

**Subgroup 4: Operational aspects**

1. What models of care have been described? Is there consensus on timing re: initiation on ACP?

**Psychosocial Model:** <sup>1,2</sup>

Conceptual model that states that primary aims of ACP are psychosocial, to be achieved while patient is competent. These goals prepare the patient for death by (1) confronting the reality of death, (2) achieving a sense of control and <sup>3</sup> strengthening relationships (with loved ones – not healthcare professionals (HCP)). The primary aim of ACP is NOT to direct patient treatment when she becomes incompetent. “ACP provides a way for individuals to confront death in the context of their love ones”.

- One explanation for failure of ACPs is that patients achieve their psychosocial goals before completing their AD form.
- Studies underestimate the effectiveness of ACP because they not measure the psychosocial goals that are important to patients.
- SUPPORT study failed to show benefit because it contextualized ACP as occurring in the primarily in the setting of HCP (not loved ones), and emphasized administrative and clinical outcomes, not psychosocial ones. <sup>3</sup>
- AD form is a tool that can provide framework to facilitate discussion and meet the goals of ACP, not end in itself.
- Role of HCP is supportive: raise the issue, provide tailored information, direct to appropriate resources, and review process including AD form completion, and finally get involved in eol care.
- Prevailing pessimism around ACP related to misunderstanding of patients goals with respect to ACP rather than failure of ADs and ACPs to achieve those goals.

**Patient-centred ACP Model:** <sup>4</sup>

- Evolution of ACP beyond document driven treatment decision-focused to patient-centred approach focusing on broader goals of treatment and commencing much earlier in course of illness. <sup>4</sup>
- Emphasis on building relationships, and shared decision making rather than completing AD. Desired outcomes promote patients quality of life, respect patients goals and autonomy, yet maintaining hope and enhance close relationships <sup>1,2</sup>,
- The outcome of this model is not number of completed AD but improving overall satisfaction with eol experience and matching outcomes with patient preferences
- **PC-ACP** integrates ACP facilitation skills of Respecting Choices with representational approach interview format designed to ensure true decision-making approach among patients/family and

HCP<sup>5</sup>. Steps: →1. Representational assessment (explore patient illness experience → 2. Explore concerns (explore patient misconceptions that can lead to eol issues concerns) → 3. Create conditions for conceptual change (review misconceptions and impact on decision-making re:eol issues) → 4. Introduce replacement information: educate patient with regard specific disease and kinds of decisions that may need to be made by proxy →5. Summary (discuss benefits of new information<sup>5</sup>  
\_PC-ACP uses Statement of Patient Preference (STP) tool. This documents patients' preference in 4 possible clinical situations that have major impact on quality of life.

#### **Integrated Model:** <sup>6</sup>

- Supportive care available from diagnosis to death; frankness about prognosis and quality of life with CKD important
- Interdisciplinary approach to care involves palliative care specialists, psychologists working with renal team in care of patient. Ever more important as more patients opt for no dialysis
- In addition to decision making and eol life issues maximizing quality of remaining life requires social and psychological support
- Overlap between restorative care and palliative care, minimize toxicity of treatment and symptoms of disease
- Care of the carers important. Require social, psychological, spiritual support
- Effective communication between multidisciplinary team and carers is essential especially when disease is advanced

#### **Respecting Choices Model** <sup>7</sup>

- Widely used in Oz
- Show that coordinated systematic, patient-centred approach by trained non-medical facilitators improve outcomes for patients and experience of family
- Essential elements of this model:
  - #1. Employ trained non-medical facilitators (drs don't have time). ACP welcomed by patients
  - #2. Patient centred: encourages open discussion about patient goals of care, values and beliefs. Patients have opportunity to document specific treatment preferences (CPR, ventilation). Focus is on realistic achievable goals of care.
  - #3. Include family and loved ones in the discussions
  - #4. Completion and filing of correct documentation
  - #5. Education of HCP. Emphasis on understanding and respecting/compliance of patient choices.

#### **RIA Structured Model** <sup>8</sup>

- Patients with chronic diseases need effective ACP
- Patients value ACP
- Opportunities exist for ACP
- Structured Process helpful:
  - #1. Initiate a guided discussion
  - #2. Introduce subject of ACP and offer information
  - #3. Prepare and complete ACP documents
  - #4. Review patients' preferences on regular basis and update document
  - #5. Apply patients' wishes to actual circumstances

#### **Disease-specific Advance Care Planning (DS-ACP) Model** <sup>9</sup>

- Uses trained facilitator
- Guides discussion between patient and proxy

- Looks at patient values and goals for treatment using worst case scenarios
- Develops a disease-specific documentation plan
- Identifies resources needed

**Timing**

- No standard of care
- Dialysis patients experience progressive decline over months to years, with episodic acute setbacks. Point at which patients reach terminal phase not easy to establish. Cognitive deterioration also part of the illness and therefore discussions should be initiated while patients are cognitively intact <sup>4</sup>.
- Another suggestion is that at minimum ACP should be introduced when the surprise question suggest patient will not survive next 12 months <sup>10</sup>
- Supportive care not solely of use at eol but adjunct to management at all stages of illness <sup>11</sup>
- ACP to be reviewed automatically at yearly or when any events that effect health/life occur <sup>4</sup>

2. What aspects of patient experience and outcomes have been studied using these models?

- This question has been addressed by Subgroup C (see p. 40 of Work Group 3 writeup).

Authors	Sample Size	Study Subjects	Study Design	ACP Intervention	Outcomes (active vs. control)
Schneiderman et al 1992 <sup>1</sup>	204	Adult outpatients with 5-year life expectancy <50%.	Single-center RCT (academic US medical center)	Training sessions for physicians In-person or mailed advanced directions instructions and forms AD placed in patient's active medical record	Quality of well-being: p>0.2 Sense of Coherence: p>0.2 Patient satisfaction: p>0.2 Locus of Control: p=0.2 % with DNR order: 60% vs. 80%, p=0.2 Mean ICU days : 2.5 vs 3.1, p>0.2 Narcotic charges: \$4885 vs. \$3590, p>0.2
SUPPORT Investigators 1995 <sup>9</sup>	4804	Adult inpatients with advanced stage chronic disease or organ dysfunction (not ESRD) in ICU or General-Specialty Medicine service	Multicenter Cluster (physician-level) RCT at 5 academic US medical centers	Skilled nurse meeting with patients and family Prognostic information shared with pt. and physician	Incidence and Timing of DNR Orders: OR=1.02 (0.9-1.15) Pt-Physician Agreement on CPR preferences: OR=1.22 (0.99-1.49) Days in ICU/coma: RR=0.97 (0.98-1.07) % in moderate-severe pain: OR=1.15 (1.00-1.33) Hosp Resource Use: RR=1.05 (0.99-1.12)
Detrerer et al 2010 <sup>3</sup>	309	>=80 years old acute care Medicine inpatients	Parallel-group RCT; single-center (academic Australian medical center).	Trained non-physician facilitators meeting with patients and family;	% of deaths with EOL wishes known and followed: 86% vs. 30%, p<.001) Family Very satisfied with quality of death: 83% vs. 48%, p=.002 Depression scale: 0 vs. 5, p=.001 Anxiety scale: 0 vs. 3, p=.03 Death in ICU: 0% vs. 15%, p=.03
Kirchhoff et al. 2010 and 2012 <sup>4,10</sup>	338	ESRD with co-morbidity (N=141) or advanced CHF (N=197)	parallel-group RCT; dual-center (Wisconsin USA)	Trained non-physician facilitators meeting with patient and surrogate; five-stage interview process 60-90 minutes, with documentation of patients'	Patient's wishes regarding CPR concordant with end-of-life care provided: 1/62 (experimental) vs. 6/48 (p=NS) Concordance of surrogates' responses to goals of treatment with patient's response: Experimental vs. control: OR=2.0-5.4 (p<.01) Knowledge of ACP (score out of 10 max): 8.3 (experimental) vs. 7.5 (control) p=.001

Song et al 2005 <sup>5</sup>	32	>50 years with semi-elective cardiac surgery	Parallel group RCT, single-center	Trained nurse facilitator meeting 20-45 minutes; five-stage interview process with patient and surrogate(s) with documentation of disease-specific statement of treatment preference.	Patient-surrogate concordance regarding EOL preference: 2.8±0.6 (experimental) vs. 1.4±1.0; p=.002 General ACP knowledge: p=NS Difficulty in making choices (decisional conflict – lower score = less conflict): 2.0±0.5 vs. 2.3±0.3; p=.02 Anxiety: p=NS for both patient and surrogate
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See also contribution by Subgroup 2 (Bekker and Schell)

3. What organizational, health economic and professional aspects of models of care have been studied?

- SUPPORT study looked at 9105 seriously ill patients, nurse facilitated interaction between patients and physicians. Intervention failed to improve care outcomes, including physicians’ knowledge of their patients’ wishes into of resuscitation. <sup>3</sup> And
- Increasing documentation of pre-existing ADs not associated with a reduction of resource use. <sup>12</sup>
- Systematic evaluation of economics of ACP lacking <sup>13</sup> Preliminary findings suggest that costs ACP programmes may be outweigh the benefits (systematic review).
- ACP programmes should not primarily be instruments to contain costs; on other hand if it is shown to contain costs, should it one of the goals? <sup>13</sup>.
- Molloy <sup>14</sup> RCT suggests that ACP reduces costs by reducing hospitalization, without effecting mortality or patient satisfaction.
- AD limiting eol care was associated with lower Medicare spending; lower in-hospital death and greater use of hospices <sup>15</sup>

Article	Intervention	Study Type	Cost measure	Findings	Trend
Malloy et al. 2000	Let Me Decide AD program	RCT	Average total costs per patient (18m)	Can\$ 3,490 (LMD) vs. Can\$ 5,239 (C)	↓
Chambers et al. 1994	∅ (documented AD discussion)	Observational study	Total charges of last hospitalization	\$30,478 (AD) vs. \$95,305 (C)	↓
SUPPORT Study 1995	Skilled nurse ⇔ facilitate ACP	Cluster-RCT	Modeled based on Therapeutic Intervention Score	Adjusted resource use ratio 1.05	=
Engelhardt et al. 2006	Advanced Illness Coordinated Care Program (AICCP)	Cluster-RCT	Health care costs (3 m) (n=169!)	\$12,123 (AICCP) vs. 16,295 (C) n.s.!	(↓)
Edes et al. 2006	Home-based Primary Care ⇔ “AD discussion”	Longitudinal study	Health care costs (6 m) (n=43!)	Net cost-savings \$1,873 per patients	↓
Zhang et al. 2009	∅ (has MD discussed EOL-wishes?)	Observational study	Medical costs in last week of life	\$1,876 (EOL-disc.) vs. \$2,917 (C)	↓
Hamlet et al. 2010	Telephonic EOL-counseling	RCT	Medicare costs	\$40,363 (EOL-C.) vs. (C) \$42,276	↓

4. Which models or organizational aspects have been tested for cultural fit or have had equality impact assessments?

- None that I could find. Studies all in developed countries, usually white, middle class, and elderly patients. In some studies non-English speakers excluded. Several studies acknowledged the lack of generalizability of findings in other cultures.

- A RCT study on 203 patients on peer mentoring in eolC of long-term dialysis patients suggested that this technique more successful in African-American (AA) patients. In African and other minorities oral traditions dominate. Important to acknowledge cultural differences and tailor approach thus enhancing trust and participation <sup>16</sup>

- Peek found that among 974 patients AA preferred shared decision making as much as whites and were more likely to report initiating more discussions with their doctors about their diabetes care. This suggests that patient preference or patient behaviors may be an unlikely cause of racial differences in shared decision making. <sup>17</sup> She also suggests combining tailored education with shared decision-making as a promising strategy for empowering low-income African-Americans. <sup>18</sup>

- In a recent report ACP was deemed relevant and helpful in this South African context. Factors for consideration included sensitivity to diverse cultural and individual preferences, available resources to meet preferences, wider participation in discussion among collectivist-oriented societies, and the role of gender in family decision making. <sup>19</sup>

5. What is the evidence for impact of model of care on experience, symptom control and outcomes?

- is this not better covered by the group dealing with symptom relief?

6. Is there sufficient knowledge and/or evidence for a preferred model of care?

- I guess it depends on what the intended goals of the model are. It has been suggested that the original aim of ACP – assuring eol care congruent with patients’ wishes – be of secondary importance. The suggestion is that focus should be the preparation of patients and surrogates to participate with clinicians in making the best possible in-the-moment medical decisions <sup>20,21</sup>; There are a limited number of RCT studies. Excellent study by Kirchhoff <sup>22</sup> used PC-ACP model (and probably only one that includes renal patient) and that shows the model impacted on high risk patients – mainly in improving congruence between patient wishes and preferred treatment <sup>22</sup>. I am of the opinion that a new model specifically for renal patients’ needs to be developed using aspects of all the models.

7. What are the key research questions for a complex intervention study of models of care in renal supportive and EoLC?

- More studies are required that confirm ACP adds value to the care of patients and their families.



- What benefits accrue to patients?
  - Does it save costs or not?
  - What model works the best or should a new one be developed?
  - What is the impact of cultural beliefs on the use of ACPs?
  - How can ACP be introduced in resource constrained environments?
  - Would ACP be of use in developing countries? If so, how do we promote its use?
8. Discuss new approaches to facilitate and improve ACP (education, communication skills training...) and evidence of their effectiveness.
  9. Discuss implementation issues in countries with availability and access to dialysis, those with availability but limited access to dialysis, and those with essentially no availability for long-term dialysis.

Dr. O'Donoghue: Other issues that are relevant: these are perhaps more pragmatic and not as high level as the above ones. Perhaps more of a reminder for me.

- how to deal with conflict between patient-family and HCP in terms of ACP
- how to deal with situations that ACP didn't make allowance for
- At what point should ADs be invoked?
- Do we not need to define terms that we use better so we all have the same understanding?

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## Work Group 4: Initiation, Withholding, and Withdrawal of Dialysis

1. ***Impact of culture and religion on end of life decision making and management***
  - a. Statement about need to be aware of cultural differences regarding end of life management
  - b. Impact of cultural differences on end of life management in advanced economies
    - i. UK evidence
    - ii. US evidence
    - iii. Emerging themes regarding lower uptake of palliative care by ethnic minorities in advanced economies
    - iv. **Question: should we include statement about ethnic minorities being at higher risk of developing advanced kidney disease and then make recommendations about how to address these issues for patients with kidney disease or suggest further research**
  - c. Religion and end of life management
    - i. Summary of information for major religions
    - ii. **Potential recommendation: need to increase awareness among renal healthcare workers about different religions attitudes and thereby enhance cultural awareness**
  - d. End of life decisions and care in different countries
    - i. Review of information reviewed
    - ii. South American information from Group 1 symptom document
    - iii. **Question: do we need to collate more evidence about other countries / regions or is this an impossible task**
    - iv. **Potential recommendation: need to be aware of country differences when writing consensus statements about palliative care**
  - e. Dialysis withdrawal and ethnicity in Western countries
    - i. Review existing data from US and Australia
  - f. Ethics of truth telling related to ethnicity and culture
    - i. Review data related to country and culture
    - ii. **Potential recommendation: need to be culturally aware during patient discussions**



**2. Provision of patient education and involvement in decision making**

- a. Rationale for provision of patient education and involvement in decision making
  - i. Difficulties in relation to withholding and withdrawal
  - ii. Quality of available information regarding natural history of CKD5 treated by dialysis or conservative care
- b. Identifying dialysis patients approaching end of life
- c. Decisions regarding withholding / withdrawal
  - i. Involvement of carers
  - ii. Engaging with palliative care
  - iii. Resolving conflict about withholding / withdrawal
- d. **Potential recommendation: patients with advanced CKD 4 and 5 should have access to education and be involved in decisions about their care**

**3. Variations in pre-ESRD care and dialysis initiation and withholding in developed economies**

- a. Patients needing acute start RRT
- b. Initiation / withholding / withdrawal of RRT
- c. **Potential recommendation / knowledge gap: to be identified**

**4. Cost-effectiveness of renal replacement therapy, palliative care and hospice**

- a. Costs and cost effectiveness of maintenance dialysis
- b. Costs for hospice care for patients with ESRD
- c. Benefits of palliative care for non-ESRD patients
- d. Costs and cost-effectiveness of palliative care
- e. **Knowledge gap: to be identified**

**5. Withdrawal and healthcare provision in countries with palliative care services**

- a. European survey
- b. **Knowledge gap and recommendations**

**6. Healthcare funding and system impact on dialysis initiation / withholding in emerging economies**

- a. Prevalence of dialysis related to financial support
  - i. Gap between initiation and prevalence
- b. Withdrawal of dialysis
- c. Withholding of dialysis
- d. Information from survey sent to nephrologists from emerging economies
- e. **Knowledge gaps to be identified**

**7. Ethics around forced withdrawal of dialysis for non-medical reasons**

- a. Review and relevance of RPA guidelines
- b. Practice in India
- c. Taiwan experience
- d. Indian experience of withdrawing life support
- e. **Knowledge gap: non-medical reasons for withdrawal of dialysis, timing of discussions**

**Conclusions and Questions**

1. Possible areas for recommendations
  - a. Need to be culturally aware
  - b. Should enable conversations with patients and families about withholding and withdrawal
  - c. Documentation of withdrawal of dialysis for financial reasons
  - d. Access to palliative care after withdrawal
  - e. Any others?
  
2. What areas have we not explored and should we do so?
  - a. Definition of withdrawal for registry purposes
  - b. Existing registry data about withdrawal rates
  - c. When should withdrawal be discussed
  - d. Trial of dialysis and withdrawal compared to withholding and conservative care

3. Potential knowledge gaps and areas of research
  - a. Can access to palliative care and withdrawal of dialysis for ethnic minorities in Western countries be improved?
  - b. Can principles of care based on patient autonomy be developed in countries / societies where this is not the case?
  - c. Natural history of CKD 5 treated with supportive care in countries where access to dialysis is not uniform
  - d. Information about variability of attitudes towards and access to withholding and withdrawal in different countries
  - e. Does promotion of end of life education for nephrology healthcare workers improve outcomes?
  - f. Would recommendation of including education on supportive care in nephrology curricula improve outcomes?
  - g. Cost effectiveness of healthcare systems that enable patient decision making and palliative / supportive care
  - h. Any others?

### Work Group 5: Conservative Care

1. How much need for conservative care is there, and what is the availability of conservative care, considering low, middle and high-income countries? How can we extrapolate from national and international renal registry data given the very little evidence that is available? What are other existing guidelines on conservative care?
2. Is there any evidence on the costs and/or cost-effectiveness of conservative care, including overall healthcare costs and resource utilization, and measures such as decreased hospitalization/bed-days, change in place of care/place of death, etc.?
3. What is the comparative evidence on survival (comparing conservative vs dialysis), considering other outcomes such as hospitalization, hospital days, quality of life etc.?
4. What is the evidence on current models of conservative care and describe what best practice in conservative care looks like (remembering low, middle and high income countries).
5. Is there evidence on whether and how conservative care can improve patient and family outcomes (i.e., outcome is defined as “a change in health status following the interventions” and including bereavement outcomes for family). What is the evidence (largely qualitative) on perspectives on conservative (non-dialytic) care, including patient and family perspectives, and also professional perspectives?