

ESRD Functional Status TEP Summary Report

May 7 & May 8, 2014

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ESRD Functional Status Technical Expert Panel Summary

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop functional status measurement tools for use in the assessment of End Stage Renal Disease Medicare beneficiaries. The purpose of the project is to develop measures that can be used to provide quality care to Medicare beneficiaries. Ideally, the developed measurement tools will:

- effectively harmonize with those tools developed for other acute and post-acute care settings
- reflect the needs of ESRD dialysis patients
- contribute to a standardized tool set across these different settings, and
- support the development of related or important quality measures

Technical Expert Panel Objectives

The objectives of the ESRD Functional Status TEP were described in the charter that was approved by the TEP members prior to the in-person meeting. Members of the TEP were tasked with providing expertise and advising UM-KECC on the appropriateness of currently available functional status assessment tools in other acute and post-acute care settings for application in the ESRD setting, and the need for revision or additional development of these tools prior to implementation in the dialysis care setting. As part of this evaluation, the TEP was asked to consider opportunities to harmonize dialysis functional status tools and data elements with similar tools and data elements previously developed for dialysis facilities and other care settings. The TEP was to provide, where appropriate, specifications for draft functional status quality measure(s), including recommendations for data collection requirements, which will be used to facilitate the collection of the necessary elements for the development and testing of future functional status measures. In addition, TEP members were to consider elements to include in potential measures using the CMS framework and that of the National Quality Forum (NQF). The four evaluation criteria for consideration are: *importance, scientific acceptability, feasibility, and usability.*

Technical Expert Panel Meeting

The Functional Status Technical Expert Panel (TEP) met in Baltimore, MD on May 7 and May 8, 2014.

The TEP was comprised of individuals with the following areas of expertise and perspectives:

- Academic Representatives
- Provider/Industry
- Rehabilitation Experts
- Geriatric Specialists
- CARE Tool Experts
- Dialysis Consumer Subject Matter Experts

The following individuals participated in this TEP:

Name	Title	Organization	Perspective	Conflict of Interest Disclosure
Manjula Kurella Tamura, MD, MPH	TEP Chair Associate Professor	Stanford University; Palo Alto VA Health Care System	Academic	Received speaker honoraria from satellite healthcare in 2013.
Lawrence Miller, MD	TEP Co-Chair <i>Clinical Professor of Medicine/Geriatric Medicine</i>	University of California-Los Angeles	Neuromuscular assessment/geriatrics	None
Mark Unruh, MD, MS	<i>Associate Professor/ Division Chief/ Solomon, Gardner & Sterling Research Chair</i>	University of New Mexico Albuquerque	Academic	None
Stephen Seliger, MD, MS	<i>Associate Professor of Medicine/Attending Physician</i>	Baltimore VA Medical Center; University of Maryland	Academic	Prior recipient of research funding from Amgen, Inc.
Michelle Richardson, PharmD, BCPS	<i>Director Of Communications/ Director, Dialysis Outcomes Programs ; Director, Outcomes Monitoring Program</i>	Tufts Medical Center, Boston, MA; Dialysis Clinic, Inc., Nashville, TN	Provider/industry	None**
Len Usvyat, PhD	<i>Senior Director</i>	Integrated Care Analytics; Fresenius Medical Care	Provider/industry with data expertise	None**
Nancy Kutner, PhD	<i>Professor of Rehabilitation Medicine/Professor of Sociology</i>	Emory University	Rehab/geriatrics	None
Debra Hain, PhD, APRN, ANP-BC, GNP-BC	<i>Assistant Professor/Nurse Practitioner</i>	Christine E Lynn College of Nursing, Florida Atlantic University; Cleveland Clinic Florida	Nurse	None
Barbara Gage*, PhD	<i>Managing Director/Fellow</i>	Brookings Institution	CARE Tool expert	Worked with CMS in the development of the CARE Tool Item Set
William Dant	Patient; Member	Alliance for Home Dialysis Innovation and Accountability Committee; Accountability Committee	Patient	None
David White	Patient; Member	Patient Advisory Committee; Medical Review Board Mid Atlantic Renal Coalition (MARC)	Patient	None
* Non-voting TEP member				
** No additional conflicts of interest stated outside of employment association				
Contract Staff				
Joe Messina, MD	Collegiate Professor of Nephrology and Professor of Internal Medicine	UM-KECC		None
Vahakn Shahinian, MD, MS	Associate Professor of Internal Medicine	UM-KECC		None
Erik Roys, MA, MS	Applications Programmer/Research Analyst	UM-KECC		None
Casey Parrotte	Research Analyst/Project Manager	UM-KECC		None
Caitlin Hanna	Research Analyst	UM-KECC		None

1. Introduction

This report summarizes the discussions and recommendations of the ESRD Functional Status Technical Expert Panel (TEP) meeting convened on May 7 and May 8, 2014 in Baltimore, MD, as well as the pre-TEP teleconference calls on March 28 and April 23, 2014, and the follow-up teleconference call on June 4, 2014. The consideration of potential measurement of functional status for both physical and cognitive function was informed by a review of relevant clinical guidelines and literature as part of an environmental scan conducted by UM-KECC. Potential measure elements were evaluated using the criteria for clinical performance measures adopted by the National Quality Forum (NQF) and CMS. These criteria include each measure's importance, scientific acceptability, feasibility, and usability.

2. Specific Considerations for the ESRD Population

The objectives of this TEP were recognized as unique due to the lack of available data related to functional status in ESRD patients. As a result, the TEP was asked to focus their discussion on identifying potential data elements that should be used to inform the future measurement of functional status in the ESRD population.

CMS and UM-KECC have been working on developing a test bed of dialysis facilities to utilize for alpha testing that will establish the feasibility and validity of any data elements the TEP decides to implement in a functional status quality measure. Additionally, CMS intends to implement the data elements identified as relevant to the measures and feasible for collection through alpha testing in CROWNWeb and enter into agreements with a sample set of dialysis facilities to voluntarily submit these data elements on a regular basis. CMS stressed that this measure development process is necessary for future implementation in quality efforts and is expected to extend over several years. A future meeting will occur in 2017 once the measure testing is completed. The TEP will be presented with the data and asked to inform any additional modifications to the measure specifications.

The TEP also recognized that while the ESRD population collectively has lower baseline functional status compared to the general Medicare population, many ambulatory ESRD patients will have a substantially better status than patients in the acute or post-acute care setting in which many of the instruments under consideration were developed. In light of this hierarchy, special considerations of floor and ceiling effects were discussed.

3. Overview of Measure Areas to be Discussed

The ESRD Functional Status TEP was asked to consider the following topic areas: the scope of Functional Status (physical, cognitive, or both) in the ESRD population, appropriate tool(s) for measurement of functional status in the ESRD population, and the method of measurement for functional status in the ESRD population. Additionally, the TEP felt it was important to discuss the reliability and accuracy of patient-reported and care-giver reported versus provider-reported assessment methods. Finally, the TEP was asked to consider both process measures and outcome measures, and will be asked to make a final recommendation once data are provided and reviewed.

4. Preliminary Activities

4.1 Environmental Scan and Literature Review

Prior to the in-person TEP meeting, UM-KECC presented the TEP members with a summary of existing clinical guidelines and published literature relating to physical and cognitive functional status in the ESRD

and non-ESRD populations. The main findings from the literature review performed for the environmental scan were as follows:

- 1) There is a high burden of functional impairment and decline in the ESRD dialysis population;
- 2) Cognitive impairment and depression are also prevalent in the dialysis population;
- 3) Presence of functional impairment is associated with adverse prognostic consequences, including mortality;
- 4) A number of tools have been used to assess functional status in dialysis patients in the literature, but no definitive standard has been established;
- 5) Evidence that interventions can reduce functional decline or improve functional status is currently weak, with the literature consisting of either observational studies or very small clinical trials.

As a result of the TEP's review of the literature scan, an additional ten articles and two ASN abstracts were added to the literature review and referenced during the TEP deliberations. These supplementary citations are notated with an asterisk in the annotated bibliography.

Clinical Practice Guidelines sources that were reviewed prior to the in-person TEP meeting included the Hartford Institute for Geriatric Nursing (HIGN), Renal Physicians Association (RPA), National Institute for Health and Care Excellence (NICE), Kidney Disease Outcomes Quality Initiative (KDOQI), and the Institute for Clinical Systems Improvement (ICSI). Upon the TEP's review of the guideline sources, the U.S. Preventive Services Task Force (USPSTF) recommendations on screening for cognitive impairment in older adults, which stated that there was insufficient evidence for or against screening, were also added to the environmental scan.

The main relevant findings from review of the guidelines were major recommendations from the HIGN (focused on older adults, not ESRD or kidney disease specific) and KDOQI that ongoing assessment of functional status should be performed. Our initial results indicated a lack of quality measures specific to the ESRD setting, though many sources may contribute to a more comprehensive understanding of functional status that goes beyond setting specificity.

4.2 TEP Charter

The Functional Status TEP Charter was distributed to the TEP members for review. The Charter was revised based on TEP input to differentiate clinician-reported functional status from patient-reported functional status, and to point out that the KDQOL-36 assesses functional status in addition to other important components of patient quality of life. Following these slight modifications, the Charter was approved by all eleven TEP members.

4.3 Pre-TEP Teleconference Calls

Two preliminary teleconference calls preceded the in-person TEP meeting. The March 28, 2014 pre-TEP teleconference call focused on the introduction of TEP members, the role of the TEP, the process for accessing TEP tools and resources, and the review and approval of the TEP Charter. In addition, each TEP member as well as the contractor, UM-KECC, provided their respective Conflict of Interest disclosures which are notated in the table found on page 4. TEP members and UM-KECC were additionally provided with the opportunity to restate any potential conflicts of interest during the in-person TEP meeting. The discussion from the second pre-TEP teleconference call on April 23, 2014 focused on the TEP Chair and Co-Chair announcements, data availability for analyses prepared by UM-KECC, and establishing the agenda for the in-person TEP meeting.

5. In-Person TEP Meeting

5.1 Introductory Summary Materials

UM-KECC presented to the TEP overview and summary data on the ESRD population, including incident counts, adjusted rates by age, incident and prevalent comorbidity estimates among Medicare chronic dialysis patients between 2002 and 2004, institutional status and functional status at the start of ESRD from 2005 to 2013, and the percent of patients needing assistance with Activities of Daily Living (ADLs) at the start of ESRD by facility characteristics and by dialysis organization ownership. Also included were various comparisons from the 2011 Comprehensive Dialysis Study including the percent of patients who worked for pay in the year prior to dialysis and percent currently working for pay, occupational status and examples of jobs held, adjusted activity scores among CDS participants by employment status, physical component summary from the Medical Outcomes Study Short Form-12 (MOS SF-12), percent of patients who reported frequent walking, mental component summary from the MOS SF-12, and the association of physical activity with age, race, sex, dialysis modality, vascular access, diabetes, self-reported physical functioning, body mass index, and serum albumin.

UM-KECC also presented background information on the Minimum Data Set (MDS). Scoring methods and data were provided detailing the Medicare ESRD patients with a Skilled Nursing Facility (SNF) claim in the MDS. UM-KECC emphasized that they are not yet sure of how to best utilize the data. UM-KECC also noted that the MDS data represent a sub-set of the ESRD population, and are, therefore, not representative of the range of functional capabilities of the ESRD population as a whole. UM-KECC reviewed comparisons between the general Medicare ESRD population and the MDS population by age group, sex, race, Hispanic ethnicity, time on dialysis, primary cause of ESRD, and treatment modality, noting instances which the MDS data were slightly over representative when compared to the entire ESRD population. UM-KECC also provided a description of the mean ADL scores for the MDS population for those patients that spent time in a SNF in 2009 and 2013, and mentioned the MDS form change that occurred in 2010 which may contribute to the slight increase in 2013 scores. Additionally, a separate comparison of the relationship between the MDS Cognitive Assessment item score and the mean ADL score was outlined.

In summary, the overview information provided to the TEP indicated the following:

- The elderly comprise a sizeable subset of U.S. chronic dialysis patients
- Incident chronic dialysis patients comprise a functionally diverse group
- 10-20% or more of patients are employed; 13% require ADL assistance; 7% are non-ambulatory
- Decreased physical activity is associated with:
 - Increasing age
 - Female gender
 - Diabetes mellitus as primary etiology
- Lower serum albumin levels
- 15-19% of Medicare chronic dialysis patients are admitted to SNFs per year; compared to all dialysis patients, this sub-set is more likely to be:
 - Older
 - Female
 - Of white race
 - Of non-Hispanic ethnicity
 - Diabetes mellitus or HTN as primary etiology
 - Complex vintage effect
- In MDS assessed chronic dialysis patients, poorer cognitive function is associated with increased MDS-ADL score (poorer function).

Some TEP members expressed concern over the clinical significance and accuracy of the MDS data, as well as the Medical Evidence Form (CMS 2728), asserting that measures such as independence level while attempting physical tasks may be subjective and may require patient or caregiver recall, and that collection of accurate data from patients in nursing facilities is often difficult, especially from patients who have cognitive as well as physical impairments. For these reasons, it was suggested that the functional status measure to be developed for the ESRD population be as objectively measurable as possible.

5.2 Candidate Data Elements for Measuring Functional Status

TEP members collectively identified multiple data elements that may be useful in assessing functional status in ESRD patients. These recommendations were derived from the Continuity Assessment Record and Evaluation (CARE) Item Set, the Short Physical Performance Battery (SPPB), and multiple cognitive and depressive symptom screening tools. Additional information on the respective data element sources and scoring methodologies can be found in the appendices.

5.2a. Physical Function Assessment

CARE Tool—Support Needs/Caregiver (CG) Assistance Items

E.1a-E1h (Entire Form): For each row, check if assistance is needed. If patient needs assistance, check the level of support needs/caregiver assistance on each row.

- Type of Assistance Needed:
 - E1a: ADL assistance
 - E1b: IADL assistance
 - E1c: Medication administration
 - E1d: Medical procedures/treatments
 - E1e: Management of equipment
 - E1f: Supervision and safety
 - E1g: Advocacy or facilitation of patient’s participation in appropriate medical care
 - E1h: None of the above or non-residential setting
- Support Needs/Caregiver Assistance (to be completed if the patient is identified as requiring assistance with a category above)
 - CG Able
 - CG will need training and/or other supportive services
 - CG not likely to be able/CG not able
 - CG ability unclear

CARE Tool—Core Functional Mobility Items

- **B2. Sit to Stand:** The ability to safely come to a standing position from sitting in a chair or on the side of the bed.
- **B3. Chair-to-Chair Transfer:** The ability to safely transfer to and from a chair (or wheelchair). The chairs are placed at right angles to each other.
- **B5. Mode of Mobility:** Does this patient primarily use a wheelchair for mobility?
 - 0 = **No** (if **No**, code B5a for the longest distance completed.)
 - 1 = **Yes** (if **Yes**, code B5b for the longest distance completed.)
- **B5a. Maximum Walk Distance** *or* **B5b. Maximum Wheel Distance:** Select the longest distance the patient walks/wheels and code his/her level of independence (Level 1-6) on that distance (see below). Observe performance (select only one):

- **Walk/wheel 150 ft (45 m):** Once standing, can walk/wheel at least 150 feet (45 meters) in corridor or similar space;
 - **Walk/wheel 100 ft (30 m):** Once standing, can walk/wheel at least 100 ft (30 meters) in corridor or similar space;
 - **Walk/wheel 50 ft (15 m):** Once standing, can walk/wheel at least 50 feet (15 meters) in corridor or similar space;
 - **Walk/wheel in Room Once Standing/Seated:** Once standing/seated, can walk/wheel at least 10 feet (3 meters) in room, corridor, or similar space
- **Coding (Level 1-6):** Safety and Quality of Performance—If helper assistance is required because patient’s performance is unsafe or of poor quality, score according to amount of assistance provided. Activities may be completed with or without assistive devices.
 - 6 = Independent—Patient completes the activity by him/herself with no assistance from a helper.
 - 5 = Setup or clean-up assistance—Helper SETS UP or CLEANS UP; patient completes activity. Helper assists only prior to or following the activity.
 - 4 = Supervision or touching assistance—Helper provides VERBAL CUES or TOUCHING/STEADYING assistance as patient completes activity. Assistances may be provided throughout the activity or intermittently.
 - 3 = Partial/moderate assistance—Helper does LESS THAN HALF the effort. Helper lifts, holds or supports trunk or limbs, but provides less than half the effort.
 - 2 = Substantial/maximal assistance—Helper does MORE THAN HALF the effort. Helper lifts or holds trunk or limbs and provides more than half the effort.
 - 1 = Dependent—Helper does ALL of the effort. Patient does none of the effort to complete the task.

Short Physical Performance Battery (SPPB)

(As needed, dependent on completion of CARE Tool – Core Functional Mobility Items)

1) 3-stage Balance Testing (semi-tandem, side-by-side , and tandem)

a) Side-by-side stand:

i) Patient Instructions:

- **Now I will show you the first movement.** (Demonstrate)
- **I want you to try to stand with your feet together, side-by-side, for about 10 seconds.**
- **You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.**
- *Stand next to the participant to help him/her into the side-by-side position.*
- *Supply just enough support to the participant’s arm to prevent loss of balance.*
- *When the participant has his/her feet together, ask, “Are you ready?”*
- *Then let go and begin timing as you say, “Ready, begin.”*
- *Stop the stopwatch and say “Stop” after 10 seconds or when the participant steps out of position or grabs your arm.*
- *If the participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.*

ii) Side-by-side stand Scoring:

- Time: __. __ seconds

- Score (select one): _____
 - 1 = Held for 10 seconds
 - 0 = Held for less than 10 seconds
 - 0 = Not attempted (select reason code below)

b) **Semi-tandem stand:**

i) Patient Instructions:

- **Now I will show you the second movement.** (Demonstrate)
- **I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.**
- **You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.**
- *Stand next to the participant to help him/her into the semi-tandem position.*
- *Supply just enough support to the participant's arm to prevent loss of balance.*
- *When the participant has his/her feet together, ask, "Are you ready?"*
- *Then let go and begin timing as you say, "Ready, begin."*
- *Stop the stopwatch and say, "Stop" after 10 seconds or when the participant steps out of position, or grabs your arm.*
- *If the participant is unable to hold the position for 10 seconds, record result and go on to the gait speed test.*

ii) Semi-tandem stand Scoring:

- Time: __. __ seconds
- Score (select one): _____
 - 1 = Held for 10 seconds
 - 0 = Held for less than 10 seconds
 - 0 = Not attempted (select reason code below)

c) **Full tandem stand:**

i) Patient Instructions:

- **Now I will show you the third movement.** (Demonstrate)
- **I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds.**
- **You may put either foot in front, whichever is more comfortable for you.**
- **You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.**
- *Stand next to the participant to help him/her into the tandem position.*
- *Supply just enough support to the participant's arm to prevent loss of balance.*
- *When the participant has his/her feet together, ask, "Are you ready?"*
- *Then let go and begin timing as you say, "Ready, begin."*
- *Stop the stopwatch and say, "Stop" after 10 seconds or when the participant steps out of position, or grabs your arm.*

ii) Full-tandem stand Scoring:

- Time: __. __ seconds
- Score (select one): _____
 - 2 = Held for 10 sec
 - 1 = Held for 3 to 9.99 seconds

- 0 = Held for < 3 seconds
 - 0 = Not attempted (select reason code below)
- d) If participant did not attempt test, select reason below:
- a. Tried but unable
 - b. Participant could not hold position unassisted
 - c. Not attempted because tester felt unsafe
 - d. Not attempted because participant felt unsafe
 - e. Participant unable to understand directions
 - f. Participant refused
 - g. Other (specify): _____
- e) Total Balance Tests Score: _____
- 2) 4-meter Walk Test (usual gait speed)
- a) **First Gait Speed Test:**
- i) Patient Instructions:
- **Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it.**
 - **This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.**
 - *Demonstrate the walk for the participant.*
 - **Walk all the way past the other cone [or other end of tape] before you stop. I will walk with you. Do you feel this would be safe?**
 - *Have the participant stand with both feet touching the starting line.*
 - *When I want you to start, I will say: "Ready, begin." When the participant acknowledges this instruction say: "Ready, begin."*
 - *Press the start/stop button to start the stopwatch when the participant steps over the starting line.*
 - *Walk behind and to the side of the participant. Stop timing when one of the participant's feet is completely across the end line.*
- ii) Trial # 1 Scoring:
- Time: __. __ seconds
- b) **Second Gait Speed Test:**
- i) Patient Instructions:
- **Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course.**
 - *Have the participant stand with both feet touching the starting line. When I want you to start, I will say: "Ready, begin." When the participant acknowledges this instruction say: "Ready, begin."*
 - *Press the start/stop button to start the stopwatch when the participant steps over the starting line.*
 - *Walk behind and to the side of the participant.*
 - *Stop timing when one of the participant's feet is completely across the end line.*

ii) Trial # 2 Scoring:

- Time: __. __ seconds

c) **Total 4-meter Walk (Gait speed) Score:**

- What is the time of the faster of the two walks? (*If only 1 walk was completed, record that time*): __. __ seconds
- Score (select one): _____
 - 0 = unable to do walk
 - 1 = Time is >8.70 sec
 - 2 = Time is 6.21-8.70 sec
 - 3 = Time is 4.82-6.20
 - 4 = time is <4.82 sec

d) If participant did not attempt test, select reason below:

- a. Tried but unable
- b. Participant could not hold position unassisted
- c. Not attempted because tester felt unsafe
- d. Not attempted because participant felt unsafe
- e. Participant unable to understand directions
- f. Participant refused
- g. Other (specify): _____

e) Aids used for this walk:

- None
- Cane
- Other (specify): _____

3) Chair Rise Task (Repeated Chair Stands)

Always use the same chair for this test

a) **Safety Assessment:**

i) Patient Instructions:

- **Let's do the last movement test. Do you think it would be safe for you to try to stand up from a chair without using your arms?**
- **The next test measures the strength in your legs. Demonstrate and explain the procedure. First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest.**
- **Please stand up keeping your arms folded across your chest.** Record result.
- *If the participant cannot rise without using arms, say "Okay, try to stand up using your arms." This is the end of the test. Record result.*

ii) Safe to stand without help? (select one): Yes No

iii) Results:

- Participant stood without using arms → Go to repeated Chair Stand Test
- Participant used arms to stand → End test; score as 0 points
- Test not completed → End test; score as 0 points

b) **Repeated Chair Stand Test:**

i) Patient Instructions:

- **Do you think it would be safe for you to try to stand up from a chair five times without using your arms? Demonstrate and explain the procedure.**
- **Please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. I'll be timing you with a stopwatch.**
- *When the participant is properly seated, say: "Ready? Stand" and begin timing.*
- *Count out loud as the participant arises each time, up to five times*
- *Stop if the participant becomes tired or short of breath during repeated chair stands.*
- *Stop the stopwatch when he/she has straightened up completely for the fifth time.*
- *Also stop if:*
 - Participant uses his/her arms
 - After 1 minute, if participant has not completed all 5 rises
 - At your discretion, if concerned for participant's safety
- *If the participant stops and appears fatigued before completing the five stands, confirm this by asking, "Can you continue?"*

ii) Repeated Chair Stand Test Scoring:

- Number of Stands Completed (select one): 1 2 3 4 5
- Time: ____seconds (if five stands are completed)
- Chair Stand Ordinal Score: ____
 - 0 = participant unable to complete 5 chair stands, or completed in >60 s
 - 1 = ≥ 16.70 sec
 - 2 = 13.7-16.69 sec
 - 3 = 11.20-13.69 sec
 - 4 = ≤ 11.19 sec

c) If participant did not attempt test, select reason below:

- a. Tried but unable
- b. Participant could not hold position unassisted
- c. Not attempted because tester felt unsafe
- d. Not attempted because participant felt unsafe
- e. Participant unable to understand directions
- f. Participant refused
- g. Other (specify): _____

4) Scoring for Complete Short Physical Performance Battery:

- a) Total Balance Test score: _____
- b) Gait Speed Test score: _____
- a) Chair Stand Test score: _____
- b) **Total Score (sum of all scores): _____**

Range: 0 (worst performance) to 12 (best performance)

5.2b. Cognitive Testing

CARE Tool—Brief Interview of Mental Status (BIMS), and Clock-drawing Test

- **B3a. Repetition of Three Words (sock, blue, bed):** Ask patient: *“I am going to say three words for you to remember. Please repeat the words after I have said all three. The words are: sock, blue, and bed. Now tell me the three words.”*

Number of words repeated by patient after first attempt:

- 3 = Three
- 2 = Two
- 1 = One
- 0 = None

After the patient’s first attempt say: *‘I will repeat each of the three words with a cue and ask you about them later: sock, something to wear; blue, a color; bed, a piece of furniture.’* You may repeat the words up to two more times.

- **B3b. Year, Month, Day**
 - **B3b.1:** Ask patient: *“Please tell me what year it is right now.”*
Patient’s answer is:
 - 3 = Correct
 - 2 = Missed by 1 year
 - 1 = Missed by 2 to 5 years
 - 0 = Missed by more than 5 years or no answer
 - **B3b.2:** Ask patient: *“What month are we in right now?”*
Patient’s answer is:
 - 2 = Accurate within 5 days
 - 1 = Missed by 6 days to 1 month
 - 0 = Missed by more than 1 month or no answer
 - **B3b.3:** Ask patient: *“What day of the week is today?”*
Patient’s answer is:
 - 2 = Accurate
 - 1 = Incorrect or no answer
- **B3c. Recall:** Ask patient: *“Let’s go back to the first question. What were those three words that I asked you to repeat?”* If unable to remember a word, give clue (i.e. something to wear; a color; a piece of furniture) for that word.
 - **B3c.1.** Recalls “sock”?
 - 2 = Yes, no cue required
 - 1 = Yes, after cueing (“something to wear”)
 - 0 = No, could not recall
 - **B3c.2.** Recalls “blue”?
 - 2 = Yes, no cue required
 - 1 = Yes, after cueing (“something to wear”)
 - 0 = No, could not recall
 - **B3c.3.** Recalls “bed”?
 - 2 = Yes, no cue required
 - 1 = Yes, after cueing (“something to wear”)
 - 0 = No, could not recall
- **Clock-drawing Test***

*(*A specific version of the Clock-drawing Test and scoring methodology will be determined prior to implementation in alpha testing.)*

- **Patient Instructions:** Instruct the patient to draw the face of a clock with all of the numbers on the clock face. Once drawn, ask the patient to draw the hands of the clock to read 10 after 11.
- **Scoring:** A correct response is all numbers placed in approximately the correct positions AND the hands are pointing to the 11 and 2.

5.2c. Depressive Symptom Screening

- Patient Health Questionnaire: PHQ-2* or PHQ-9

**As a result of the post-TEP follow up teleconference discussion, TEP members recommended the PHQ-2 over the PHQ-9. See section 7.2 Depressive Symptom Screening for discussion.*

5.3 Timing and Frequency of Functional Status Assessment

- Assessment should occur within 90 days of admission to the facility and annually, thereafter
- Assessment should occur prior to starting a dialysis session rather than post-treatment
- Additional assessment should be done at the discretion of the provider, as the patient's condition requires

5.4 Exclusions

Possible exclusions were discussed and TEP members agreed on the following exclusion criteria:

- Pediatric patients (<18 years)
- Hospice status patients
- Transient patients and patients in a facility for less than 90 days
- If the measures are ultimately developed as process measures, then exclusion for "appropriate intervention" should be considered

5.5 Summary of TEP discussion for the proposed measure data elements

The TEP members agreed that dialysis facilities are not currently the health care provider with responsibility for many of the health needs of dialysis patients, beyond a limited number of well-defined metrics. The TEP felt that expansion of dialysis providers' responsibility for the care of the patient beyond the dialysis procedure could improve patient wellness, but also acknowledged that facilities face multiple barriers, such as a lack of resources or staff, or the fact that many facilities are not currently set up to address elements of functional status. The TEP was asked to frame the subsequent functional status discussion around the notion of "how care should be provided", rather than "how care is currently provided" to maximize identification of opportunities for improvement in our care of chronic dialysis patients.

The TEP members considered whether the functional status assessment paradigm should include facility-level accountability for the results of the assessment, either through appropriate referral for rehabilitation and other services, or for the functional status of the facility's patients as a health outcome directly. The discussion of this issue included a review of National Quality Forum (NQF) perspectives on process and outcome metrics as well as the level of evidence required for NQF approval of these types of metrics. Alternative constructs were explored, ranging from one in which dialysis facilities are viewed as a source for functional status data, responsible for testing and reporting only, to a construct in which dialysis facilities were responsible for the functional status outcomes/status of the patients treated there. An intermediate construct was defined in which dialysis facilities were seen as being responsible for measuring functional status and acting on the results, by providing appropriate referral to rehabilitation and other specialized care providers to act on the identified functional limitations. Although some TEP

members believed that dialysis facilities were in a position to provide functional status assessment and initiate referral for identified rehabilitation services, others countered that appropriate referral services may not be available in all geographic areas, particularly in rural areas. Many TEP members were not satisfied that the current level of clinical evidence could justify development of an outcome measure(s) for dialysis facilities at this time. There was consensus among TEP members that measurement of functional status, beyond the current practice of evaluating patients with the KDQOL instrument, would provide additional specific information regarding patient functional status.

The TEP considered a wide range of instruments in their deliberations, including the Functional Independence Measure (FIM), Kidney Disease Quality of Life survey (KDQOL-36), Continuity Assessment Record and Evaluation (CARE) Item Set, and the Short Physical Performance Battery (SPPB). The TEP recognized that the Kidney Disease Quality of Life survey (KDQOL-36) is already widely used in the dialysis provider community as a self-reported instrument, and is thought to be highly predictive of overall decline in health. The TEP discussed the effectiveness of the self-reported KDQOL-36 as a measure of functional status and raised concerns about the potential for patients to under-report their limitations in functional ability. The TEP also pointed out that the SF-12 (the physical and mental component subset of the KDQOL-36) was intended to be a population-based instrument rather than to report on quality of life outcomes in order to monitor individual patients. TEP members ultimately felt that the KDQOL-36 was a measure of overall health status and quality of life, and did not offer the same level of detail to assess functional status as the clinician-reported instruments, such as the CARE Tool and SPPB, specifically when assessing how well the patient performs ADLs. As a result, the TEP decided to pursue elements based on the CARE Tool, Short Physical Performance Battery (SPPB), Clock-drawing Test, and Patient Health Questionnaire as outlined below.

5.6 Justification for Physical Function Assessment

As the TEP pointed out, rehabilitation was an essential part of the initial goal of maintenance dialysis but the focus of treatment today relies much more heavily on easily measurable biochemical parameters. CMS aims to address the unmet needs within the dialysis population, and identify various opportunities to slow functional decline.

5.6a Continuity Assessment Record and Evaluation (CARE) Item Set

The Continuity Assessment Record and Evaluation (CARE) Item Set is a standardized assessment tool developed by CMS that is used to measure a patient's medical, functional, cognitive, and social support status across acute and post-acute care settings (including long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies). The CARE Tool set is designed to be completed by a professional, and requires special training to ensure accurate administration and coding. While the CARE Item Set was not specifically tested in the ESRD dialysis setting, the sample selected was representative of the entire Medicare population. Additionally, each individual item from the CARE Tool set has been validated as part of and separate from its subset.

For the purposes of the TEP, UM-KECC utilized the CARE Home Health Admission Tool Form for review. The data elements relevant to the TEP discussion for application to the ESRD population were all available in this specific form and representative of similar elements in other CARE Tool presented to the TEP prior to the in-person meeting.

Upon review, the TEP found many of the items included in the comprehensive CARE Tool set not applicable for the dialysis facility setting, as they would be difficult to observe directly. As a result, the TEP narrowed the focus of the discussion to the following item sets believed to provide the most feasible and accurate assessment of physical function in the ESRD population:

5.6a.1 Support Needs/Caregiver (CG) Assistance Items

The TEP considered the CARE Tool Support Needs/Caregiver Assistance item set that addresses broad areas in which a patient may need assistance, in addition to the Supplemental Functional Ability items, which assess level of skill in greater detail. The TEP found the item set that assesses a patient's broader needs (Part II, Items E.1a-E.1h) to hold a higher level of relevance to the ESRD population than the supplemental items, and recommended its implementation into the future quality measure. Furthermore, the shortened survey minimizes burden imposed on both the patient and provider.

Item set E.1a-E.1h (Type of Assistance Needed) from Part II. Admission Information, Support Needs/Caregiver (CG) Assistance is intended to identify needs in the following areas: Activities of Daily Living (ADL) assistance, Instrumental Activities of Daily Living (IADL) assistance, Medication administration, Medical procedures/ treatments, Management of equipment, Supervision and safety, and Advocacy or facilitation of patient's participation in appropriate medical care. This item set is intended to be completed through a patient interview; however, if there is suspicion that the patient's report is not accurate the professional can instead turn to a caregiver/proxy for an alternative source. Furthermore, the TEP recommended that the examples provided on this form be revised to more specifically relate to the ESRD population. For example, 'management of equipment' might refer to home dialysis supplies.

5.6a.2 Core Functional Mobility Items

In addition to the supplemental items mentioned above, multiple Core Functional Mobility Items (such as "lying to sitting on side of bed" and "toileting transfer") were also eliminated by the TEP due to the fact that they would be difficult to directly observe in the dialysis setting. The final set of selected Core Functional Mobility Items from Part VI, Admission Information, include "sit to stand" (B2), "chair-to-chair transfer" (B3), "mode of mobility" (B5), and "maximum walk/wheel distance" (B5a/B5b). The TEP discussed the distance parameters for the maximum walk/wheel distance (1. Walk 150 ft., 2. Walk 100 ft., 3. Walk 50 ft., 4. Walk in room once standing/seated) and noted that most facilities are unlikely to have 150 feet of continuous space to utilize for the purposes of this test. TEP members agreed that patients could alternatively walk three laps of a 50 foot distance instead.

TEP members shared concern of a ceiling effect that may be involved with the CARE Tool set, as the instrument may not sufficiently capture higher levels of functioning as may be present in ambulatory ESRD patients. Due to this likelihood, the TEP agreed it would be advantageous to implement the joint use of the Short Physical Performance Battery (SPPB) and the selected CARE Tool items, as necessary, in hopes of capturing a wider range of functioning.

5.6b Short Physical Performance Battery (SPPB)

The Short Physical Performance Battery (SPPB) includes a 3-stage balance test (side-by-side, semi-tandem, and full), measurement of gait speed, and a repeated chair stand (timed). It has been shown to be highly predictive of subsequent disability, and has been measured across a wide range of populations including the dialysis population and those with congestive heart failure and pulmonary disease. Further discussion brought to the attention of the TEP the fact that the SPPB was designed to include impaired and dependent patients and has been used in patients with stages 3 and 4 CKD. This tool provides a great deal of normative data that can indicate trends of decline. Additionally, the results of reliability testing of this battery have been widely published.

While discussing the Short Physical Performance Battery (SPPB) some TEP members voiced safety concerns, though overall the TEP felt these concerns weren't any greater than the risk posed by a wheelchair patient moving into the dialysis facility. Additionally, technicians and Resident Nurses should already be trained to assess fall risk. Similar to the concern of a ceiling effect evident in the CARE tool set for ambulatory patients, the TEP raised the concern of a floor effect evident in the SPPB, as roughly 10%

of the dialysis population are non-ambulatory and may be unable to perform the battery tasks. This reinforced the proposal to incorporate the supplementary use of the SPPB when a patient performs at the maximal level on the CARE items identified above. TEP members reached consensus and felt this battery measured complex physical movements that could provide a more accurate measure of dialysis patients' functional mobility.

5.7 Justification for including Cognitive Testing

The TEP agreed that cognition is an important aspect of functional status and determinant of the patient's ability to manage his/her disease including the ability to manage medications, live independently, and participate in care decisions. The TEP also noted the high prevalence of cognitive impairment within the dialysis population, and discussed several issues related to the measurement of cognition in dialysis patients and implementation of cognitive screening in dialysis facilities.

The potential benefits of screening for cognitive impairment were reviewed including the identification of reversible causes of cognitive impairment, and reduction in morbidity from neurocognitive disorders through pharmacotherapy, education, improved decision-making and caregiver support. Potential harms of screening were also considered including the potential for false positive test results, anxiety, depression, or stigma as a result of a neurocognitive disorder diagnosis. The uncertain and potentially small benefit from available interventions for neurocognitive disorders was raised as well as some concern about the validity of cognitive testing in non-English speaking patients. Thus, adequate education of providers, patients, and family members on cognitive screening, cognitive impairment, and potential actions is required to abrogate these potential harms.

Finally, the TEP discussed whether cognitive screening results are actionable, and agreed that possible consequences of a positive screening test might include referrals for more extensive neuropsychiatric testing, neuroimaging, evaluation of patient safety, caregiver support, and pharmacotherapy. The TEP recommended that cognitive testing should be performed in a quiet area without distractions, such as the social worker's office, whenever possible.

5.7a CARE Tool—Brief Interview for Mental Status (BIMS), and Clock-drawing Test

Instruments considered in the discussion regarding the measurement of cognitive function included the Mini-Mental State Exam, the CARE Brief Interview for Mental Status (BIMS), the Six-Item Screener (SIS), the Mini-Cog, the Clock drawing Test, and multiple memory-recall exercises. The TEP noted a high prevalence of executive dysfunction among dialysis patients and therefore recommended that potential cognitive screening instruments include a measure of executive function. The TEP agreed to further investigate the joint use of the CARE Tool Brief Interview for Mental Status (BIMS) item set and the Clock drawing Test. Once data are collected from the facilities via alpha and beta testing, the TEP will revisit the feasibility of including cognitive testing as part of a functional status quality measure for dialysis patients. Data collection should include elements of feasibility, patient perceptions of cognitive screening, diagnostic testing and interventions resulting from cognitive screening, and effect of cognitive screening on functional status and quality of life.

5.8 Justification for including Depressive Symptom Screening

The TEP considered the possibility of including a depressive symptom screening in the assessment of functional status, and pointed out that those who work in area of rehabilitation have included such testing in the collection of functional status for many years. The TEP referred to the Comprehensive Dialysis Study (CDS) (Kutner, 2009, 2010, 2012) and responses from ACTIVE-ADIPOSE study participants' data results indicating that depression is common among dialysis patients, and is a major concern that dialysis patients would like their providers to be aware of. Additionally, the CDS results indicate that

depression has a large impact on patients' lives and function, including their ability to remain employed and their adherence with dialysis treatments. Furthermore, the TEP noted that treatment for depression, both pharmacologic and non-pharmacologic, has been shown to be effective in dialysis patients, albeit in small studies, and access to treatment is generally available to most patients and dialysis facilities.

5.8a PHQ-2 and PHQ-9

The TEP reached consensus on further examining the possibility of including one of two variations of the Patient Health Questionnaire, PHQ-2 or PHQ-9, and pointed out that the PHQ-9 has been validated in the ESRD population. Other instruments, such as the Beck Depression Inventory and Center for Epidemiologic Studies Depression Scale were discussed, but felt to be too lengthy to be practicable for clinical use. The TEP will reconvene once measure testing data are provided and decide if depressive symptom screening is a feasible option in the dialysis setting.

5.9 Justification for Timing and Frequency of Measurement

The TEP agreed that functional status assessment should occur within a reasonable period (90 days of admission to the facility) to allow for baseline measurement, and should be performed on an annual basis thereafter to help identify and track functional decline. Furthermore, consensus was reached that additional assessment should be performed at the discretion of the provider, as the patient's condition requires. In discussing hospital readmissions, the TEP decided that trying to account for linked and non-linked hospital readmissions would be extremely difficult, so each hospital readmission should be treated as a separate event. TEP members also agreed that assessment of functional status should occur prior to starting a dialysis session as opposed to post-treatment. Pre-treatment assessment aims to avoid any potential effect immediately following dialysis that some patients can experience such as weakness and low blood pressure.

5.10 Justification for Exclusions

Possible exclusions were discussed and TEP members agreed on the exclusion of pediatric patients (<18 years), given that the identified data elements from the CARE Tool and SPPB have not validated in the pediatric population. TEP members also agreed that patients on hospice status may not be appropriate for attempts at rehabilitative or other intervention efforts, and should therefore be excluded as well. Furthermore, the TEP felt it unreasonable to hold facilities responsible for transient patients or patients in a facility for less than 90 days, and that any referrals or interventions performed may not be conducive for the patient if only at facility for a short while.

5.11 Feasibility

There are various feasibility issues to address when discussing the implementation of a functional status measurement tool. One of the largest concerns is that of additional burden upon both patients and providers, as CMS does not currently collect or publicly report measures of functional status for the ESRD population, and the data are thus not currently collected or reported by dialysis facilities. Assessment would also require additional time above and beyond the typical appointment, as testing would need to occur prior to a dialysis session. Furthermore, there may also be logistical barriers, such as the need for a quiet and private space while administering both physical and cognitive testing, though the on-site social worker's office could likely serve this purpose.

5.12 Usability

As mentioned above, CMS does not currently collect or publicly report measures of functional status for the ESRD population. As measures are developed and data become available, functional status may be included in quality improvement, quality assurance, and performance evaluation efforts. Ongoing development and testing will include consideration of usability and applicability of resulting measures to these efforts.

5.13 Measure Area Gaps for the ESRD Population

Fulfilling the need for reliable and validated measures of patient functional status for the ESRD population is the immediate goal of this TEP. However, additional gaps in data availability and measure specification are identified below:

Referral for rehabilitative care: While patient functional status is the focus of the current measure development, TEP members considered whether dialysis facilities could act on functional status information and whether the referral or treatment of patient functional difficulties should also be measured.

Scope: Quality of life as well as mood, pain, emotional, and social functioning are all potential aspects of the broader scope of functional status.

Risk adjustment: Given the possibility that functional status measures could be used for dialysis facility performance evaluation, the availability of relevant data for risk adjustment should be considered alongside measure testing data for functional status when the TEP reconvenes.

5.14 In Person TEP Meeting Conclusion and Follow-up Plan

The TEP developed consensus regarding the importance of developing specific functional status assessment tools for assessment of chronic dialysis patients by dialysis providers. The TEP also acknowledged the lack of clinical evidence supporting dialysis facilities' role in interventions designed to directly improve the functional status of dialysis patients with functional impairment. The TEP discussed potential process quality measures based on functional status measurement and reporting alone, and alternatively as measures that evaluated the facilities' referral to rehabilitation experts for treatment of the patients identified with functional status deficits. The TEP deferred recommendations regarding this aspect of quality measure definition until analyses of functional status assessment in chronic dialysis patients, planned as part of the Measures Testing Program (described above in section 2. *Specific Considerations for the ESRD Population*), are available.

Consideration was given to the scope of Functional Status, as well as to a wide variety of existing tools and instruments. While there may be feasibility barriers to face, the TEP agreed that physical and cognitive functional decline are important factors to consider in the dialysis setting. While some additional burden is justifiable in order to support patient wellness, great efforts should be made to keep the burden as minimal as possible.

The TEP members agreed to hold a follow-up teleconference to revisit these decisions and to further consider specific screening tools for evaluation of depression and cognitive function.

6. Post-TEP Public Comment Period

A public comment period was held at the conclusion of the In-Person TEP Meeting on May 8, 2014. Due to a delay in the posting of the TEP meeting agenda, public attendees were unable to call in to the meeting line until after the meeting discussion had concluded. Public comments were then received by two members of the dialysis provider community; these comments can be found in Appendix D.

7. Follow-up TEP Teleconference Call

Following the in-person TEP meeting, it was determined that a follow-up call was necessary to refine the selected data elements, and to further inform the potential implementation of depressive symptom screening and cognitive testing as a functional status quality measure(s).

7.1 Physical Function Assessment

The TEP reviewed the draft physical function data elements proposed at the in-person TEP meeting and offered additional clarification on their respective specifications.

7.1a. CARE Tool—Support Needs/Caregiver (CG) Assistance Items

The TEP reviewed the Admission items (E1a through E1h) found in the CARE Tool—Home Health Admission Assessment item set, and agreed to utilize the form in its entirety, including both the “Support Needs/Caregiver Assistance” items and the “Type of Assistance Needed” items. The TEP clarified that the Caregiver items should be completed only when a patient is identified as requiring assistance in a respective category. Additionally, TEP members agreed on a tiered approach for form completion that would allow the clinician to decide whether this item set is based on patient report, a proxy, or both. Furthermore, the TEP reiterated the need to revise the examples provided on this form to more specifically relate to the ESRD population. For example, ‘management of equipment’ might refer to home dialysis supplies.

7.1b. CARE Tool—Core Functional Mobility Items, with SPPB (As needed, dependent on completion of CARE Tool – Core Functional Mobility Items)

The TEP briefly reviewed the proposed Core Functional Mobility items from the CARE Home Health Admission Assessment form (B2-B5b) and agreed upon the supplementary use of the Short Physical Performance Battery (SPPB) when patients reach the ceiling score of this CARE item set. No further specifications were required.

7.2 Depressive Symptom Screening

The TEP continued to consider the possibility of including screening for depressive symptoms in the assessment of functional status and reviewed multiple studies indicating the severity and prevalence of depression within the dialysis population. A recent USRDS special study utilizing the PHQ-2 and a sample of incident patients on either peritoneal dialysis (PD) or hemodialysis (HD) demonstrated a depressive symptom prevalence rate of approximately 27% to 28%. Similarly, an alternate USRDS study that was restricted to patients on HD indicated an occurrence of depressive symptoms in about 24% of patients based on a CES-D score of 18 or higher.

The TEP commented on the validation of the Beck Depression Inventory (BDI), but considered it to be too labor-intensive, and once again focused their deliberations on the use of the PHQ-2 or PHQ-9. The heightened sensitivity of the PHQ-9 was discussed, though the TEP felt it did not necessarily offer a greater level of specificity, and therefore could not justify the additional survey length. As such, the TEP recommended the implementation of the PHQ-2 for depressive symptom screening.

The NQF usability criteria were considered and the TEP noted that depressive symptom screening would require a structured diagnostic interview to track the number of patients that utilized referrals, such as referrals for mental health care. The TEP additionally expressed concern over the fact that rural communities may not have access to appropriate referral sources; however, the TEP pointed out that such communities may have other resources to utilize, such as a social worker and take-home brochures and

pamphlets. Consensus was reached on the implementation of a process measure that would later offer the ability to track whether or not a referral was made.

7.3 Cognitive Testing

The importance of assessing cognitive impairment within the dialysis population was reiterated, as it is prevalent in about 20-30% of patients and is thought to be widely unrecognized and undocumented. TEP members discussed reversible and non-reversible impairment, and briefly reviewed concerns and challenges previously outlined in the in-person meeting including diagnostic testing, additional medication and side-effects, stigma, labeling, and other social consequences. Additional challenges may include the low level of specificity offered by many cognitive testing instruments, as well as a lack of validation within the ESRD population.

TEP members reconsidered several instruments including the MoCA, KDQOL-36, Mini-Mental State Exam, the CARE Tool Brief Interview for Mental Status (BIMS), the Six-Item Screener (SIS), the Mini-Cog, and the Clock-drawing Test. Some of these instruments, such as the MoCA and KDQOL-36, were eliminated due to their extensive length, lack of validity, or potential for inaccurate patient reporting.

The TEP recommended that cognitive testing be included as part of functional status assessment for ESRD patients on a preliminary basis until the results of pilot testing can be reviewed, and the feasibility and usability of such a measure can be examined in greater depth. The TEP agreed to pursue a combined candidate measure comprised of the CARE Tool—Brief Interview of Mental Status (BIMS) item set and the Clock-drawing Test. The TEP noted the possibility of implementing a revised scoring system for the Clock-drawing Test. A specific Clock-drawing Test and scoring methodology will be selected prior to implementation in alpha testing.

8. Summary

- 1) The TEP developed consensus regarding the importance of developing specific functional status assessment tools for assessment of chronic dialysis patients by dialysis providers.
- 2) The TEP also acknowledged the paucity of clinical evidence supporting dialysis facilities' role in interventions designed to directly improve the functional status of dialysis patients with functional impairment. The TEP discussed potential process quality measures based on functional status measurement and reporting alone, and alternatively as measures that evaluated the facilities' referral to rehabilitation experts for treatment of the patients identified with functional status deficits. The TEP deferred recommendations regarding this aspect of quality measure definition until analyses of functional status assessment in chronic dialysis patients, planned as part of the Measures Testing Program (described above in section 2. *Specific Considerations for the ESRD Population*), are available.
- 3) Consideration was given to the scope of Functional Status, as well as to a wide variety of existing tools and instruments. While there may be feasibility barriers to face, the TEP agreed that functional decline is an important factor to consider in the dialysis setting. While some additional burden is justifiable in order to support patient wellness, great efforts should be made to keep the burden as minimal as possible.
- 4) In summary, the data elements recommended by the Functional Status TEP are as follows :
(See section 5.2 *Candidate Data Elements for Measuring Functional Status* for additional details)

Physical Function Assessment

- CARE Tool—Support Needs/Caregiver (CG) Assistance Items
- CARE Tool—Core Functional Mobility Items
- Short Physical Performance Battery (SPPB), As needed, dependent on completion of CARE Tool— Core Functional Mobility Items

Cognitive Testing

- CARE Tool—Brief Interview of Mental Status (BIMS)
- Clock-drawing Test
(Specific test and scoring methodology will be determined prior to testing)

Depressive Symptom Screening

- Patient Health Questionnaire 2 (PHQ-2)
Ask Patient: “Over the past 2 weeks, how often have you been bothered by any of the following problems?”
 - 1) Little interest or pleasure in doing things
 - 0 = Not at all
 - 1 = Several days
 - 2 = More than half the days
 - 3 = Nearly every day
 - 2) Feeling down, depressed, or hopeless
 - 0 = Not at all
 - 1 = Several days
 - 2 = More than half the days
 - 3 = Nearly every day
- 5) The TEP recommended that cognitive testing be included as part of functional status assessment for ESRD patients on a preliminary basis until the results of pilot testing can be reviewed, and the feasibility and usability of such a measure can be examined in greater depth. The discussion regarding cognitive function testing was notable for general agreement that accurate assessment of functional status is influenced by patient cognitive function. However, several TEP members raised concerns about the overall utility of cognitive function assessment, specifically with regard to the accuracy and precision of tools, actionability, and potential unintended consequences.
- 6) The proposed data elements described in this summary report are intended to reflect the initial deliberation of the Functional Status TEP during the pre-TEP teleconference calls, the in-person TEP meeting, and the post-TEP teleconference call. These draft measure specifications will continue to be modified throughout the development process.

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10. Appendices

- A. TEP Charter
- B. Annotated Bibliography
- C. Clinical Guidelines & Measures
- D. Post-TEP Public Comments
- E. Link to access the Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Volumes 1-3) and the CARE: Home Health Admission Tool
- F. Short Physical Performance Battery (SPPB)

Technical Expert Panel (TEP) Charter

TEP Title: ESRD Functional Status

Name of Measure Contractor Convening the TEP: University of Michigan Kidney Epidemiology and Cost Center (UM-KECC)

Measure Project:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop functional status measurement tools for use in the assessment of End Stage Renal Disease Medicare beneficiaries. Ideally, the developed measurement tools will effectively harmonize with those tools developed for other acute and post-acute care settings, contributing to a standardized tool set across these different settings and supporting the development of related or important quality measures.

Why the standardization of function?

The concept of functional status in the area of activities has not been measured directly. Unlike height or weight, which are measured in a uniform manner using established standardized units of measure (i.e., inches, centimeters, pounds, and kilograms), functional status has no standard unit of measure or scale. Instead, functional status has traditionally been documented using subsets of specific daily activities such as eating, bathing, walking, and stair climbing, and by assessing a person's performance while completing these daily activities. A patient's level of performance for each daily activity is reported using a rating or response scale, which is a multiple-point response option set that ranks the patient's performance level. Assessment of functional status may also be based on tools that rely on patient self-report.

Although many functional assessment instruments exist, only a few instruments or items have been used to construct functional status quality metrics for performance measurement at the facility level. Additionally, no measures related to functional status exist for use across settings. Each post-acute care provider collects patient assessment data that are unique to that type of provider, e.g., nursing home. Although similar clinical and functional status data are collected on the MDS, IRF-PAI, and OASIS, the item definitions, measurement scales, data collection procedures, and time frames differ such that data collected on these respective items are not directly comparable. Without a standardized data set for use across settings, or for use in multiple settings, there is limited ability to fulfill multi-setting quality measurement harmonization or standardization. This is particularly relevant in that quality measures designed for multi-setting use could promote

care coordination and transition planning efforts for patients who receive care from multiple provider types.

The standardization of functional status measures are derived from the Continuity Assessment Record and Evaluation (CARE) Tool. The Deficit Reduction Act of 2005 mandated the use of standardized assessments across acute and post-acute settings. The Post-Acute Care Payment Reform Demonstration (PAC-PRD), developed from the DRA mandate, included testing the reliability of the standardized items when used in several Medicare settings (NHs, HHAs, LTCHs, and IRFs). The idea for standardization across PAC settings would create a generalizable “language” across all PAC settings in which care coordination, care transition, and a more detailed tracking of quality and performance is possible. Standardized assessment data would communicate the same data across care settings, ensuring the increased reliability and validity of the data, facilitating patient centered care, improving outcomes, and reducing provider burden. CMS has undertaken this work in an effort to develop standardized assessment items and quality measures for each of those settings.

While dialysis facilities were not among the settings included in the PAC-PRD, functional status is important in this population and is one component of patient quality of life that is assessed by the KDQOL-36. The KDQOL-36 is a patient-reported instrument measuring functional status and quality of life, whereas the CARE Tool set is a provider-reported instrument measuring functional status. The purpose of this Technical Expert Panel is to develop quality measures assessing the functional status of the ESRD population that are aligned with similar measure development efforts taking place in other Medicare settings.

TEP Objectives:

The Technical Expert Panel will include experts in biostatistics, disparity in care, measure development, functional status assessment, as well as care providers, patients, and dialysis stakeholders. Functional status experts will provide knowledge and perspective regarding development and implementation of functional assessment tools and measures in other acute and post-acute care settings. Members of the TEP are tasked with advising UM-KECC on the appropriateness of currently available functional status assessment tools for application in the ESRD setting and the need for revision or additional development of these tools prior to implementation in the dialysis care setting. As part of this evaluation, the TEP will consider opportunities to harmonize dialysis functional status tools and data elements with similar tools and data elements previously developed for other care settings. If appropriate, the TEP will provide specifications for draft functional status quality measure(s), including recommendations for data collection requirements, which will be used to facilitate the collection of the necessary elements for the development and testing of a future outcome driven functional status measure.

Specifically, this TEP will be charged with developing recommendations to advise UM-KECC in future development of an outcome measure focusing on Functional Status for Medicare dialysis patients in the United States. The TEP recommendations should, at a minimum, include 1) identification of high-impact functional status areas for development, 2) evaluation of the available evidence supporting measure development in each area; 3) assessment of data collection feasibility, and 4) suggestions for risk adjustment strategies, if indicated.”

Scope of Responsibilities:

The role of each TEP member is to provide advisory input to UM-KECC in the development of a Functional Status Measure for the US ESRD population.

Role of UM-KECC: As the CMS measure developer contractor, UM-KECC has a responsibility to support the development of quality measures for ESRD patients. The UM-KECC moderators will work with the TEP chair(s) to ensure the panel discussions focus on the development of draft measure specifications as recommended to the contractor. During discussions, UM-KECC moderators may advise the TEP and chair(s) on the needs and requirements of the CMS contract and the timeline, and may provide specific guidance and criteria that must be met with respect to CMS and NQF review of candidate measures.

Role of TEP chair(s): Prior to the in-person TEP meeting, one or two TEP members are designated as the chair(s) by the measure contractor and CMS. The TEP chair(s) are responsible, in partnership with the moderator, for directing the TEP to meet the expectations for TEP members, including provision of advice to the contractor regarding measure specifications.

Duties and Role of TEP members: According to the CMS Quality Measure Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to suggest candidate measures and related specifications, review any existing measures, and determine if there is sufficient evidence to support the proposed candidate measures. The level of supporting evidence is expected to vary by measure area.

TEP members are expected to participate in two to three pre-meeting teleconferences during March and April 2014, attend one in-person meeting on May 7 and 8, 2014 in Baltimore, MD, and be available for additional follow-up teleconferences and correspondence as needed in order to support the submission and review of the candidate measures by NQF. Some follow up activities may occur after data collection and testing has occurred.

The TEP will review, edit (if necessary), and adopt a final charter at the first teleconference. A discussion of the overall tasks of the TEP, and the goals/objectives of the ESRD quality measurement project will be described. TEP members will be provided with a summary of current guidelines and literature prior to the in-person meeting. TEP members will be

asked to submit additional studies to be included in the literature review. A review of the CMS and NQF measure development criteria will also be covered during the teleconference.

During the In-Person Meeting on May 7 and 8, 2014, in Baltimore, MD: The TEP will review evidence to determine the basis of support for proposed measures within each of the measure areas. The key deliverables of the TEP at the in-person meeting include:

- recommending candidate measures if there is sufficient evidence to support the measures,
- recommending draft measure specifications,
- assisting in completing the necessary documentation forms to support submission of the measures to CMS for review, and to the NQF for endorsement
- as needed TEP members may be asked to provide input to UM-KECC as they prepare responses to public comments

At the end of the two day meeting the TEP chair(s) and TEP members will prepare a summary of recommendations. As necessary, the TEP chair(s) will have additional contact with UM-KECC moderators to work through any other issues. This will include votes for draft and final measures. After the In-Person Meeting (approximately May – August, 2014): TEP members will review a summary report of TEP discussions, recommendations, measure specifications, and other necessary documentation forms required for submission to the NQF for endorsement.

Guiding Principles:

Potential TEP members must be aware that:

- Participation on the Technical Expert Panel is voluntary.
- Input will be recorded in the meeting minutes.
- Proceedings will be summarized in a report that is disclosed to the general public.
- If a TEP member has chosen to disclose private, personal data, that material and those communications are not covered by patient-provider confidentiality.
- Potential patient participants may keep their names confidential, if they wish to do so.
- All questions about confidentiality will be answered by the TEP organizers.
- All potential TEP members must disclose any current and past activities that may pose a potential conflict of interest for performing the tasks required of the TEP.
- All potential TEP members must commit to the expected time frame outlined for the TEP.
- All issues included in the TEP summary report will be voted on by the TEP members
- Counts of the votes and written opinions of the TEP members will be included, if requested.

Estimated Number and Frequency of Meetings:

- ◆ TEP members should expect to come together for one to three teleconference calls prior to the in-person meeting on May 7 and 8, 2014, in Baltimore, MD.
- ◆ The in-person meeting on May 7th and 8th will last from ***** to *****.
- ◆ After the in-person meeting, additional conference calls may be needed.

Member Composition:

Attach the Technical Expert Panel Roster form.

Subgroups (if needed):

End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support

Functional Status Technical Expert Panel Annotated Bibliography

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**Citations that are preceded by an asterisk are indicative of recommendation by a member of the Functional Status Technical Expert Panel, and as such were incorporated in to the bibliography after UM-KECC's initial literature scan.*

Overview

Literature Review Summary

UM-KECC's Literature Review and Environmental Scan supporting functional status quality measure specification for chronic dialysis facilities began in October 2013. Information describing the KDQOL-36 tool for measuring patient reported QoL, including physical function and information describing the development of the CARE Tool Set used to assess health and function across multiple post-acute care settings outside of the ESRD community were reviewed by the Functional Status team. As a result of subsequent discussions with CMS, a series of searches were undertaken iteratively to identify pertinent PubMed content describing development and validation of functional assessment tools, associations between functional status and primary outcomes, and results of interventional studies in both ESRD and other post-acute settings.

PubMed searches were executed in January 2014 based on the search criteria established by the group. Initial PubMed search results were screened for general topic applicability prior to a focused review by two clinician investigators associated with the team. TEP members were asked to provide additional citations of relevance, and one resulting article citation was incorporated into the literature review.

A search using the terms "functional status AND ESRD" elicited 417 results, of which 84 articles were deemed relevant for potential review. An accompanying search using the terms "functional status AND ESRD AND assessment" was performed, resulting in an additional 21 articles. A search for "frailty AND dialysis" yielded 63 results, 26 of which were deemed relevant to this project. An alternate search using the terms "functional status AND ambulatory" resulted in 1051 articles, of which 167 abstracts were determined to be relevant and included in the first round of review. A search was then performed using the terms "functional characteristics AND dialysis", and an additional 12 of 263 articles were determined to be relevant. Additional search criteria were utilized to complete searches for "functional capacity AND ESRD", which resulted in 31 relevant articles out of 223 results, and a search for "functional capacity AND ambulatory", which contributed 19 additional relevant articles from a list of 368 results.

The references identified through this literature search were merged and duplicates were deleted, resulting in a master list of approximately 332 articles. A preliminary review investigating the potential relevance of each article generated a condensed list of approximately 124 articles to be used for the functional status technical expert panel annotated bibliography. The existing guidelines and measures were included in the bibliography, along with a list of referenced instruments. The bibliography was broadly divided into two sections, one relating specifically to the ESRD or ESRD relevant context, and the other to non-ESRD settings. Each section was further organized into studies describing a) the prevalence of functional status limitations, b) the development and/or validation of functional status instruments, c) interventions directed at improving functional status, d) outcomes associated with limited or declining functional status and e) qualitative or systematic reviews of topics pertaining to functional status.

Environmental Scan Summary

In order to identify existing guidelines and quality measures that may be relevant and applicable to assessing functional status in the ESRD community, UM-KECC performed a preliminary scan of the leading quality measure databases, inventories, and measure development programs. Some of the

resources utilized in our efforts during January 2014 include the National Quality Forum (NQF), the National Quality Measures Clearinghouse (NQMC)—via the Agency for Healthcare Research and Quality (AHRQ), the National Institute for Health and Care Excellence (NICE), the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI), Kidney Disease Improving Global Outcomes (KDIGO), European Best Practices (EBP), and Caring for Australians with Renal Impairment (CARI). Our initial results indicated a lack of quality measures specific to the ESRD setting, though many sources may contribute to a more comprehensive understanding of functional status that transcends setting specificity.

Included in the Appendices are:

- “Classifying and Reporting Functional Status” by the National Committee on Vital Health Statistics (NCVHS)
- KDQoL36
- RAND SF-36 Scoring Rules
- RAND SF-36 Form

Information related to the Care Tool is available here: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>

ESRD

Association with Outcomes

Bao Y, Dalrymple L, Chertow GM, et al. **Frailty, dialysis initiation, and mortality in end-stage renal disease.** *Arch Intern Med.* 2012 Jul 23;172(14):1071-7.

Notes: Based on the Comprehensive Dialysis Study (n=1576), a USRDS special study of incident dialysis pts, demonstrating an association between frailty and mortality.

Abstract: BACKGROUND: In light of the recent trend toward earlier dialysis initiation and its association with mortality among patients with end-stage renal disease, we hypothesized that frailty is associated with higher estimated glomerular filtration rate (eGFR) at dialysis start and may confound the relation between earlier dialysis initiation and mortality. METHODS: We examined frailty among participants of the Comprehensive Dialysis Study (CDS), a special study of the US Renal Data System, which enrolled incident patients from September 1, 2005, through June 1, 2007. Patients were followed for vital status through September 30, 2009, and for time to first hospitalization through December 31, 2008. We used multivariate logistic regression to model the association of frailty with eGFR at dialysis start and proportional hazards regression to assess the outcomes of death or hospitalization. RESULTS: Among 1576 CDS participants included, the prevalence of frailty was 73%. In multivariate analysis, higher eGFR at dialysis initiation was associated with higher odds of frailty (odds ratio [OR], 1.44 [95% CI, 1.23-1.68] per 5 mL/min/1.73 m²; P < .001). Frailty was independently associated with mortality (hazard ratio [HR], 1.57 [95% CI, 1.25-1.97]; P < .001) and time to first hospitalization (HR, 1.26 [95% CI, 1.09-1.45]; P < .001). While higher eGFR at dialysis initiation was associated with mortality (HR, 1.12 [95% CI, 1.02-1.23] per 5 mL/min/1.73 m²; P = .02), the association was no longer statistically significant after frailty was accounted for (HR, 1.08 [95% CI, 0.98-1.19] per 5 mL/min/1.73 m²; P = .11). CONCLUSIONS: Frailty is extremely common among patients starting dialysis in the United States and is associated with higher eGFR at dialysis initiation. Recognition of signs and symptoms of frailty by clinicians may prompt earlier initiation of dialysis and may explain, at least in part, the well-described association between eGFR at dialysis initiation and mortality.

Burrowes JD, Cockram DB, Dwyer JT, et al. **Cross-sectional relationship between dietary protein and energy intake, nutritional status, functional status, and comorbidity in older versus younger hemodialysis patients.** *J Ren Nutr.* 2002 Apr;12(2):87-95.

Notes: Association between dietary energy and protein intakes and functional status based on cross-sectional analysis of baseline status of pts enrolled in the HEMO study.

Abstract: OBJECTIVE: To evaluate the dietary energy intakes (DEI) and dietary protein intakes (DPI) of older (> or = 65 years), middle-aged (50 to 64 years), and younger (< 50 years) maintenance hemodialysis patients enrolled in the Hemodialysis (HEMO) Study, and to describe the relationship between age, nutritional status, functional status, and comorbidity. DESIGN: A cross-sectional

analysis of the first 1,397 participants in baseline (before randomization) was performed. MAIN OUTCOME MEASURES: DEI and DPI, serum albumin, creatinine, total cholesterol, normalized protein catabolic rate (nPCR), equilibrated nPCR (enPCR), functional status, and comorbidities. RESULTS: Mean DEI, DPI, serum albumin, creatinine, nPCR, and enPCR were significantly lower in the older compared with the younger patients, despite similar doses of dialysis as measured by equilibrated Kt/V. Mean DEI, DPI, nPCR, and enPCR were not significantly different between the middle-aged and older patients, whereas albumin and creatinine were significantly lower in the older patients. Mean dry weight and percent of standard body weight in the younger and older patients were similar. In all groups, mean DEI was lower than both the HEMO study's standard of care (SOC) and the Kidney Disease Outcomes Quality Initiative (K/DOQI) nutrition recommendations, whereas mean DPI was lower than the SOC and K/DOQI recommendations only in the middle-aged and older patients. Middle-aged and older patients had higher cholesterol, lower functional status, and more comorbidities than the younger patients. CONCLUSION: Middle-aged and older maintenance dialysis patients may be at greater risk for developing protein-energy malnutrition than their younger counterparts. Inadequate DEI and DPI reported in middle-aged and older patients were associated with lower levels of biomarkers of nutritional status, lower functional status, and higher comorbidities than in the younger patients.

*Chen IR, Wang S, Liang CC, et al. **Association of Walking with Survival and RRT Among Patients with CKD Stages 3-5.** *Clin J Am Soc Nephrol.* 2014 May 15. pii: CJN.09810913. [Epub ahead of print]

Abstract: "BACKGROUND AND OBJECTIVES: Patients with CKD can benefit from an increase in physical activity. Walking is one of the most common exercises in patients with CKD; however, the association of walking with outcomes in patients with CKD is not clear. This study investigated the association of walking with overall mortality and RRT in patients with CKD stages 3-5. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: All patients with CKD stages 3-5 in the CKD program of China Medical University Hospital from June 2003 to May 2013 were enrolled. The risks of overall mortality and RRT were analyzed using competing-risks regressions. RESULTS: A total of 6363 patients (average age, 70 years) during a median of 1.3 (range=0.6-2.5) years of follow-up were analyzed. There were 1341 (21.1%) patients who reported walking as their most common form of exercise. The incidence density rate of overall mortality was 2.7 per 100 person-years for walking patients and 5.4 for nonwalking ones. The incidence density rate of RRT was 22 per 100 person-years for walking patients and 32.9 for nonwalking ones. Walking, independent of patients' age, renal function, and comorbidity, was linked to lower overall mortality and lower RRT risk in the multivariate competing-risks regression. The adjusted subdistribution hazard ratio (SHR) of walking was 0.67 (95% confidence interval [95% CI], 0.53 to 0.84; $P < 0.001$) for overall mortality and 0.79 (95% CI, 0.73 to 0.85; $P < 0.001$) for the risk of RRT. The SHRs of overall mortality were 0.83, 0.72, 0.42, and 0.41 for patients walking 1-2, 3-4, 5-6, and ≥ 7 times per week, and the SHRs of RRT were 0.81, 0.73, 0.57, and 0.56, respectively. CONCLUSIONS: Walking is the most popular form of exercise in patients with CKD and is associated with lower risks of overall mortality and RRT. The benefit of walking is independent of patients' age, renal function, and comorbidity."

Cleary J, Drennan J. **Quality of life of patients on haemodialysis for end-stage renal disease.** *J Adv Nurs.* 2005 Sep;51(6):577-86.

Notes: A single center study (n=97) in Ireland describing SF-36 scores in patients on dialysis vs. general population, and comparison between well-dialyzed versus less well-dialyzed patients.

Abstract: AIM: The aims of the study were (a) to measure the overall quality of life of people receiving haemodialysis, (b) to compare the quality of life of the sample with that of the general population and (c) to identify any differences between the quality of life of people who are adequately dialysed and those inadequately dialysed, as determined by Kt/V(urea) (dialysis adequacy) measurements. BACKGROUND: End stage renal disease is a progressive, debilitating, chronic illness requiring nursing and medical interventions. The development of the disease affects quality of life, potentially influencing physical and mental health, functional status, independence, general well-being, personal relationships and social functioning. METHOD: A descriptive, cross-sectional, survey was carried out of the quality of life of patients undergoing haemodialysis treatment at a hospital in the Republic of Ireland. A non-probability sample of 97 patients was chosen. Health-related quality of life was assessed using the 36-item Short Form Health Survey questionnaire. FINDINGS: Patients receiving haemodialysis identified limitations in a number of areas including vitality, physical functioning and physical role limitations. They also reported significantly lower physical functioning when compared with general population norm-based scores. Differences were also found in mental health scores between patients who were well-dialysed and those less well-dialysed. CONCLUSION: End-stage renal disease and its ensuing treatments negatively affect quality of life. Nurses aware of this evidence can explore new ways to assess more accurately and identify specific problem areas for individual patients and take action to ameliorate these.

Curtin RB, Klag MJ, Bultman DC, Schatell D. **Renal rehabilitation and improved patient outcomes in Texas dialysis facilities.** *Am J Kidney Dis.* 2002 Aug;40(2):331-8.

Notes: Facility level retrospective analysis of 169 dialysis facilities in Texas demonstrating association between facility use of rehabilitation activities and facility mental component scores on SF-36.

Abstract: BACKGROUND: Because a cure is not a reasonable goal for patients with end-stage renal disease (ESRD), optimal physical and mental health functioning are primary objectives of care and major determinants of health-related quality of life, morbidity, and mortality. This cross-sectional study used facility-level survey data to test the hypothesis that dialysis unit rehabilitation activities are associated with higher patient functional status. METHODS: Data were collected from 169 dialysis facilities in the ESRD Network of Texas (Network 14), including facility characteristics, facility-level patient demographic and clinical characteristics, and facility rehabilitation activities measured by the Life Options Unit Self-Assessment Tool (USAT). Facility-level data on patient functioning and well-being measured by the Medical Outcomes Study 36-Item Short-Form Health

Survey were obtained from all 86 of the respondent facilities that collected it. RESULTS: Most participating facilities reported performing rehabilitation activities in all five categories (encouragement, education, exercise, employment, and evaluation). The median number reported was 32 of a possible 100 activities. Exercise interventions were the least often implemented activities. Linear multiple regression showed that facility rehabilitation activity scores measured by the USAT were associated with higher facility mean Mental Component Scale (MCS) scores, controlling for facility characteristics (size, profit status), facility-level patient demographic characteristics (diabetes, race, sex, age), and facility-level patient laboratory variables: urea reduction ratio and hemoglobin and serum albumin levels. CONCLUSION: Because MCS scores have been shown in other studies to be inversely related to morbidity and mortality, this finding suggests that the introduction of rehabilitation interventions into the dialysis care regimen may prove beneficial.

Evans, R W **Recombinant human erythropoietin and the quality of life of end-stage renal disease patients: a comparative analysis.** *Am J Kidney Dis.* 1991 Oct;18(4 Suppl 1):62-70.

Abstract: The clinical and quality of life outcomes of hemodialysis patients improve remarkably following treatment with recombinant human erythropoietin (Epo). However, few studies have compared the quality of life of Epo patients with that of end-stage renal disease (ESRD) patients on various treatment modalities. Data obtained in three separate studies of ESRD patients were comparatively analyzed. Over 1,500 patients from 23 dialysis and transplant centers were studied. Both objective and subjective quality of life were examined. Objective quality of life indicators included employment status, functional ability, and health status. Subjective quality of life indicators included well-being, life satisfaction, psychological affect, and happiness. Quality of life varied significantly across treatment modality, with transplant recipients generally reporting the highest levels of objective and subjective quality of life. However, hemodialysis patients treated with Epo reported a statistically significant improvement between baseline and 10 months' follow-up on all quality of life indicators, except employment. Epo patients reported a level of overall life satisfaction that exceeded that of patients on all ESRD treatment modalities. Among transplant recipients, diabetics reported the poorest quality of life, while patients on conventional immunosuppressive therapy often had a quality of life that exceeded that of patients on cyclosporine therapy. Some of these findings may be explained by case-mix differences, as well as differing study designs. Quality of life remains a significant concern among ESRD patients and the physicians and medical professionals responsible for their care. Unfortunately, the rehabilitation potential of many patients, despite the availability of Epo, and the success of transplantation, remains unmet.

Griffin KW, Friend R, Wadhwa NK. **Measuring disease severity in patients with end-stage renal disease: validity of the Craven et al. ESRD Severity Index.** *Psychol Med.* 1995 Jan;25(1):189-93.

Abstract: The validity of a recently developed measure of disease severity, the End-stage Renal Disease Severity Index (Craven et al. 1991) was examined in haemodialysis (HD) and continuous ambulatory peritoneal dialysis (CAPD) patients (total N = 82). Scores on the ESRD Severity Index

were compared with three commonly identified components of disease severity: physiological indices of severity, functional status, and psychological burden of illness. For the entire group of subjects, scores on the ESRD Severity Index were negatively associated with functional ability and positively related to physiological severity. ESRD Severity Index scores showed a weaker relationship with psychological burden of illness which depended in part on treatment mode. Disease severity scores were positively related to depression in CAPD patients but not in HD patients. These findings suggest that the ESRD Severity Index is a valuable research tool with construct validity.

Hsieh RL, Lee WC, Huang HY, Chang CH. **Quality of life and its correlates in ambulatory hemodialysis patients.** *J Nephrol.* 2007 Nov-Dec;20(6):731-8.

Abstract: BACKGROUND: In hemodialysis patients, quality of life (QOL) may vary across a range of individual conditions and social environments. In this study, we focused on ambulatory hemodialysis patients, examining their QOL compared with that of age-matched controls. Correlates of QOL in ambulatory hemodialysis patients were also examined. METHODS: QOL was evaluated by WHOQOL in ambulatory hemodialysis patients and age-matched controls. Correlations of QOL with age, sex, body mass index (BMI), functional performance, physical activity, cognitive function, psychiatric disorders, diabetes status, comorbidities, duration of dialysis therapy, adequacy of dialysis, biochemical variables and nutritional status were also examined in ambulatory hemodialysis patients. RESULTS: In WHOQOL, we found decreased psychological domain scores (19.8 vs. 21.6, $p=0.012$) and overall QOL (89.0 vs. 94.3, $p=0.035$) for ambulatory hemodialysis patients compared with age-matched controls, especially in the items: enjoying life ($p=0.032$), feeling life has meaning ($p=0.023$), having opportunity to take leisure time ($p=0.003$) and being satisfied with sexual life ($p=0.044$). Patients with male sex, BMI >24 and duration of dialysis shorter than 5 years had lower overall QOL than controls. Male dialysis patients also had lower QOL than female patients. As for correlates of QOL in ambulatory hemodialysis patients, age, BMI and psychiatric disorders were negatively correlated. By contrast, premorbid and current satisfaction with personal health were positively correlated. CONCLUSIONS: QOL in ambulatory hemodialysis patients was lower than in age-matched controls. QOL in ambulatory hemodialysis patients was positively correlated with personal health satisfaction and negatively correlated with age, BMI and psychiatric disorders.

Hung AM, Chertow GM, Young BS, Carey S, Johansen KL. **Inflammatory markers are unrelated to physical activity, performance, and functioning in hemodialysis.** *J Ren Nutr.* 2002 Jul;12(3):170-6.

Abstract: OBJECTIVE: To determine the associations among dietary intake and inflammatory cytokines with physical activity, function, and performance in maintenance dialysis patients. DESIGN: Cross-sectional analysis of cohort study. SETTING: University-affiliated dialysis units, general clinical research center. SUBJECTS: Multiethnic cohort of maintenance hemodialysis patients. MAIN OUTCOME MEASURES: Physical activity by accelerometry; physical performance by gait speed, stair climbing, and chair raising; physical functioning by the Medical Outcomes Study Short Form 36-item questionnaire subscale scores; and maximal and adjusted activity scores of human activity profile. RESULTS: Levels of inflammatory cytokines were uniformly high. Tumor necrosis factor-alpha was

directly correlated with dietary protein and energy intake; no other cytokines were directly or inversely correlated with intake. Dietary intake was associated with physical activity, as expected, and not significantly associated with performance or function (with the exception of gait speed). There were no significant associations among inflammatory cytokines and physical activity, performance, or function. **CONCLUSION:** Although dietary intake and inflammation may independently influence traditional proxies of nutritional status, this analysis provides no evidence for a link between cytokines and physical activity, performance, or function in hemodialysis patients. More research is required to understand the role of cytokines in protein energy malnutrition and the mechanisms of wasting and functional decline in the dialysis population.

Ifudu O, Paul HR, Homel P, Friedman EA. **Predictive value of functional status for mortality in patients on maintenance hemodialysis.** *Am J Nephrol.* 1998;18(2):109-16.

Notes: Large (n=522) observational study associating functional status as assessed by Karnofsky score with mortality.

Abstract: In patients receiving maintenance hemodialysis, laboratory indices (such as serum albumin concentration) are predominantly utilized to assess well-being, while measures of functional status are rarely applied. However, the serum albumin concentration declines with advancing age, and the mean age of patients starting maintenance hemodialysis is now over 63 years. Using a 14-level modified Karnofsky activity scale, we measured baseline functional status in 522 randomly selected hemodialysis patients and prospectively monitored them for 3 years to determine the predictive value of our modified Karnofsky score for mortality. At onset of study, serum albumin and creatinine concentrations as well as hematocrit were measured and the comorbid conditions documented. At baseline, the 522 subjects (270 women and 252 men) included 327 blacks (63%), 154 whites (29%), 31 Hispanics (6%), and 10 Asians (2%) of mean age 59 (SD) 15 years. The mean duration of end-stage renal disease was 4 3.6 years, and the mean serum albumin concentration was 3.7 0.4 g/dl. 166 (32%) of the patients died during the observation period. Cox regression analysis revealed inverse relations between mortality and both our modified Karnofsky score ($p = 0.0001$) and serum albumin concentration ($p = 0.001$). The predictive value of a low modified Karnofsky score for mortality persisted after analysis of subjects stratified according to serum albumin concentration (< 4 g/dl, $n = 382$, $p = 0.0001$ vs. ≥ 4 g/dl, $n = 140$, $p = 0.008$). With a modified Karnofsky score (< 70 vs. ≥ 70), the relative risk of death during the 3-year follow-up period was 1.44 (95% confidence interval 1.236, 1.675; $p < 0.0001$). Forward stepwise Cox regression analysis showed that advanced age ($p = 0.0005$), white race ($p = 0.0009$), diabetes mellitus ($p = 0.01$), and a low serum albumin concentration ($p = 0.003$) were independently associated with an increased risk of mortality during follow-up after adjustment for other factors. A modified Karnofsky score ($p = 0.14$) did not predict survival in the Cox model when other independent variables were included. We conclude that in patients with end-stage renal disease sustained on maintenance hemodialysis, a poor functional status (measured on a modified Karnofsky activity scale) is associated with early mortality. Periodic measurement of modified

Karnofsky score is a simple, low-cost, and reliable means of identifying patients on dialysis at risk for early death.

Johansen KL, Chertow GM, Jin C, Kutner NG. **Significance of frailty among dialysis patients.** *J Am Soc Nephrol.* 2007 Nov;18(11):2960-7. Epub 2007 Oct 17.

Notes: Important study, based on large cohort of dialysis pts (n=2275) who were part of the Dialysis Morbidity and Mortality Wave 2 study, demonstrating high prevalence of frailty and associations with mortality and hospitalization.

Abstract: not available

Kohl Lde M, Signori LU, Ribeiro RA, et al. **Prognostic value of the six-minute walk test in end-stage renal disease life expectancy: a prospective cohort study.** *Clinics (Sao Paulo).* 2012+ADs-67(6):581-6.

Notes: Longitudinal cohort study of HD pts (n=52) demonstrating association between six-minute walk and mortality.

Abstract: OBJECTIVES: The six-minute walk test has been widely used to evaluate functional capacity and predict mortality in several populations. Thus, the aim of this study was to evaluate the prognostic value of the six-minute walk test for the life expectancy of end-stage renal disease patients. METHODS: Patients over 18 years old who underwent hemodialysis for at least six months were included. Patients with hemodynamic instability, smoking, chronic obstructive pulmonary disease, physical incapacity and acute myocardial stroke in the preceding three months were excluded. RESULTS: Fifty-two patients (54+ACU- males+ADs- 36 years old) were followed for 144 months. The distance walked in the six-minute walk test was a survival predictor for end-stage renal disease patients. In the multivariate analysis, for each 100 meters walked with a 100-meter increment, the hazard ratio was 0.53, with a 95+ACU- confidence interval of 0.37-0.74. There was a positive correlation between the distance walked in the six-minute walk test and peak oxygen consumption (r +AD0- 0.508). In the multivariate analysis, each year of dialysis treatment represented a 10+ACU- increase in death probability+ADs- in the severity index analysis, each point on the scale represented an 11+ACU- increase in the death risk. CONCLUSIONS: We observed that survival increased approximately 5+ACU- for every 100 meters walked in the six-minute walk test, demonstrating that the test is a viable option for evaluating the functional capacity in patients with end-stage renal disease.

Kurella Tamura M, Covinsky KE, Chertow GM, et al. **Functional status of elderly adults before and after initiation of dialysis.** *N Engl J Med.* 2009 Oct 15;361(16):1539-47.

Notes: High profile national registry study of nursing home residents with ESRD documenting functional status (as assessed by MDS-ADL) before and after initiation of dialysis.

Abstract: BACKGROUND: It is unclear whether functional status before dialysis is maintained after the initiation of this therapy in elderly patients with end-stage renal disease (ESRD). METHODS: Using a national registry of patients undergoing dialysis, which was linked to a national registry of nursing home residents, we identified all 3702 nursing home residents in the United States who were starting treatment with dialysis between June 1998 and October 2000 and for whom at least one measurement of functional status was available before the initiation of dialysis. Functional status was measured by assessing the degree of dependence in seven activities of daily living (on the Minimum Data Set-Activities of Daily Living [MDS-ADL] scale of 0 to 28 points, with higher scores indicating greater functional difficulty). RESULTS: The median MDS-ADL score increased from 12 during the 3 months before the initiation of dialysis to 16 during the 3 months after the initiation of dialysis. Three months after the initiation of dialysis, functional status had been maintained in 39% of nursing home residents, but by 12 months after the initiation of dialysis, 58% had died and predialysis functional status had been maintained in only 13%. In a random-effects model, the initiation of dialysis was associated with a sharp decline in functional status, indicated by an increase of 2.8 points in the MDS-ADL score (95% confidence interval [CI], 2.5 to 3.0); this decline was independent of age, sex, race, and functional-status trajectory before the initiation of dialysis. The decline in functional status associated with the initiation of dialysis remained substantial (1.7 points; 95% CI, 1.4 to 2.1), even after adjustment for the presence or absence of an accelerated functional decline during the 3-month period before the initiation of dialysis. CONCLUSIONS: Among nursing home residents with ESRD, the initiation of dialysis is associated with a substantial and sustained decline in functional status.

Kutner NG, Brogan D, Fielding B. **Physical and psychosocial resource variables related to long-term survival in older dialysis patients.** *Geriatr Nephrol Urol.* 1997;ADs-7(1):23-8.

Abstract: The association of baseline characteristics with long-term survival (7 years past baseline interview) was investigated in a prevalent sample of 349 dialysis patients aged 60-87 at baseline. In primary diagnosis, treatment modality, and months on dialysis, the sample was representative of all patients aged 60 living in the state of Georgia. There were 38 surviving patients at a 7-year follow-up. At their baseline assessment, long-term survivors were significantly younger and less likely to report cardiovascular comorbidity. With age and cardiovascular comorbidity controlled, long-term survivors were more likely at baseline to desire a transplant, and reported needing less time to +ACI-recover+ACI- from HD treatments. Survivors' physical functioning resources at baseline included less health limitation of activity, lower functional impairment, and more frequent activity/exercise. Psychosocial well-being resources included higher self-esteem, higher sense of mastery, and higher self-rated health status. Ongoing assessment of these resource variables, with targeted interventions, might contribute to improved survival as well as improved functioning and well-being for older patients.

Kutner NG, Lin LS, Fielding B, et al. **Continued survival of older hemodialysis patients: investigation of psychosocial predictors.** *Am J Kidney Dis.* 1994 Jul;24(1):42-9.

Notes: Observational study from the ESRD Network in Georgia (n=287) demonstrating association between functional status and mortality.

Abstract: This study investigated whether social and/or psychologic factors help to predict older dialysis patients' continued survival. A stratified (by race and sex) random sample of patients aged 60 years was selected from the ESRD Network census of all patients in that age category residing in a single southeastern state (Georgia) and receiving chronic dialysis as of November 1987; personal interviews with patients were completed in 1988. This analysis includes 287 patients (mean age, 69 years) receiving outpatient hemodialysis for whom primary cause of renal failure and functional status data were complete. Patient tracking and vital statistics data determined that 49% of the sample survived as of October 31, 1990. Study variables included demographic, dialysis, health status, social situation, and psychologic outlook variables reported at the patients' 1988 interviews. Log rank tests showed univariate associations between patients' continued survival and race/gender, recovery time following dialysis treatments, cardiovascular co-morbidity, exercise activity score, freedom from health limitation of daily activity, functional status, leisure activity score, self-rated health status, overall life satisfaction, depression, and public religiosity. The Cox proportional hazards model was fit to the data, with continued survival from the time of the 1988 interview as the dependent variable. There was a significantly increased mortality risk for white men relative to the other race/gender groups and for patients reporting severely impaired functional status at the 1988 interview. With functional status in the model, no other social or psychologic variables were significant predictors of mortality.(ABSTRACT TRUNCATED AT 250 WORDS)

*Kutner NG, Zhang R, Huang Y, Wasse Haimanot. **Falls among hemodialysis patients: potential opportunities for prevention?** *Clin Kidney J* (2014) 0: 1–7

Abstract: Background. Falls among patients undergoing maintenance hemodialysis (HD) have significant consequences for quality of life and functional independence, morbidity, healthcare utilization and even mortality, but studies on the etiology of falls within large HD cohorts are limited. Methods. Falls during the past 12 months were ascertained for a prevalent multi-center HD cohort (n = 762) aged 20–92 years, and associations with demographic and treatment characteristics, comorbidities, cognitive function, prescribed medications, balance tests, frailty and depressive symptoms were assessed. Results. Falls were sustained by 28.4% of participants. In multivariable-adjusted analyses, participants classified as frail were over two times more likely to report falls [odds ratio (OR): 2.39, 95% confidence interval (CI): 1.22–4.71, P = 0.01], and participants with a CES-D score 18+ and/or prescribed antidepressants were over 80% more likely to be fallers (OR: 1.83, 95% CI: 1.23–2.74, P = 0.003) than were participants with a CES-D score <18 and no prescribed antidepressants. Conclusions. Frailty and depressed mood, factors that are potentially modifiable, are prominently associated with falls.

*Kutner NG, Zhang R, Johansen KL. **Depressed Mood, Usual Activity Level, and Continued Employment after Starting Dialysis.** *Clin J Am Soc Nephrol.* 2010 Nov;5(11):2040-5.

Abstract: "BACKGROUND AND OBJECTIVES: When patients start dialysis, their employment rate declines and disability benefits are an option. With patient sociodemographic and clinical characteristics including disability income status controlled, we investigated the significance of depressed mood and usual activity level as predictors of patients' continued employment after dialysis start. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Incident patients from 296 randomly selected dialysis clinics were surveyed in the Comprehensive Dialysis Study (CDS). Participants provided information about employment status, disability income status, education, depressive symptoms measured by the Patient Health Questionnaire-2 (PHQ-2), and usual activity level/energy expenditure measured by the Human Activity Profile. Age, gender, race, insurance, diabetes, inability to ambulate or transfer, chronic obstructive pulmonary disease, cardiovascular conditions, and hemoglobin and serum albumin values at treatment start were obtained from US Renal Data System files. Dialysis modality was defined at time of interview. RESULTS: Among 585 CDS participants who worked in the previous year, 191 (32.6%) continued working after dialysis start. On the basis of the PHQ-2 cutoff score ≥ 3 , 12.1% of patients who remained employed had possible or probable depression, compared with 32.8% of patients who were no longer employed. In adjusted analyses, higher Human Activity Profile scores were associated with increased likelihood of continued employment, and there was a borderline association between lower PHQ-2 scores and continued employment. CONCLUSIONS: Screening and management of depressive symptoms and support for increased activity level may facilitate patients' opportunity for continued employment after dialysis start, along with generally improving their overall quality of life."

*Larkin JW, McDougall KA, Usvyat LA, et al. **Depressive Affect in Incident Hemodialysis Patients: Prevalence and Risk Factors.** *ASN Expert Abstract #2387, June 2013*

Abstract: "Background: Depression is common among patients with end-stage renal disease, yet is not well studied in incident hemodialysis (iHD) patients in their first month of chronic outpatient dialysis. This study investigated the prevalence of and risk factors for depressive affect (DA) in the FMC NA RightStart Program. Methods: From a random sample of 108 dialysis centers, 429 iHD patients in their first month of dialysis at FMC NA during Jan-Mar 2013 were contacted by telephone for up to three tries for depression screening utilizing the Patient Health Questionnaire 2 (PHQ2). The PHQ2 consists of two questions that determine presence of depressed mood and anhedonia during the previous two weeks. Scores range from 0-6; a positive DA score was defined as ≥ 3 . Clinical and lab parameters were collected up to the first 120 days of dialysis and associations between DA were assessed using multivariate logistic regression. Results: Of 429 patients, 172 (40.1%) were successfully screened with the PHQ2, 192 (44.8%) could not be reached, 6 (1.4%) refused and 59 (13.8%) did not have a valid telephone number. Responders were: 41.3% females; mean age of 65.0 ± 14.6 years; 64.5% had diabetes; and 67.4% utilized dialysis catheters. The PHQ2 was positive in 23.3% of patients. Logistic regression identified male iHD patients had significantly lower risk of DA (OR=0.32, $p=0.02$), while higher log of creatinine (C r) trended towards greater risk for DA (OR=3.48, $p=0.08$). There were no associations between DA and age, diabetes, access type, ethnicity, race, body mass index, residual renal function, number of comorbidities, albumin, interdialytic weight gain, or urea reduction ratio. Conclusions: The prevalence of DA by PHQ2 was

23.3% in this iHD patient cohort, consistent with prior reports in the literature. A decreased risk for DA was observed in males. C reatinine levels may play a role as a determinant of DA, but further studies are required to better understand these associations."

Li M, Tomlinson G, Naglie G, et al. **Geriatric comorbidities, such as falls, confer an independent mortality risk to elderly dialysis patients.** *Nephrol Dial Transplant.* 2008 Apr;23(4):1396-400. Epub 2007 Dec 5.

Notes: Association between mortality and falls demonstrated in a cohort of 162 chronic HD pts. Raises possibility of evaluating occurrence of falls or fall risk as a relevant measure of functional status.

Abstract: BACKGROUND: As the number of patients aged ≥ 65 years starting haemodialysis (HD) continues to increase, more patients are at risk of falls, functional decline and cognitive impairment. In an earlier prospective cohort study, we showed that 44% of elderly HD patients had more than one fall within a 1-year period. The objective of this study was to assess whether falls remained predictive of increased mortality risk even after controlling for age, comorbidity, dialysis vintage and laboratory variables. METHODS: Using a prospective, cohort study design, patients aged ≥ 65 years and on chronic HD during the period April 2002-2003 were recruited. Patients were followed biweekly, and falls occurring within the first year were recorded. Outcome data were collected until death, study end (30 December 2006), transplantation or transfer to another dialysis centre. RESULTS: A total of 162 patients were followed for a median of 32.7 months (quartiles 14-57). In a univariate Cox model with a time-dependent variable for falls status, survival was worse amongst fallers compared to non-fallers (HR 2.13, 95% CI 1.32-3.45; $P = 0.002$). After adjustment for age, dialysis vintage, comorbidity and laboratory variables, falls were a significant predictor of mortality (HR 1.78, 95% CI 1.07-2.98, $P = 0.03$). Exclusion of falls associated with concurrent illnesses did not alter the results (HR 1.63, CI 1.02-2.28 $P = 0.05$). CONCLUSIONS: We conclude that the occurrence of more than one accidental fall in a community-dwelling HD patient aged ≥ 65 years is associated with an independent increased risk of death. As fall interventions are effective, screening HD patients for falls may be a simple measure of clinical importance.

McAdams-DeMarco MA, Law A, Salter ML, et al. **Frailty as a novel predictor of mortality and hospitalization in individuals of all ages undergoing hemodialysis.** *J Am Geriatr Soc.* 2013 Jun;61(6):896-901. Epub 2013 May 27.

Notes: Single center study of HD pts (n=146) showing association between frailty and mortality and hospitalizations.

Abstract: OBJECTIVES: To quantify the prevalence of frailty in adults of all ages undergoing chronic hemodialysis, its relationship to comorbidity and disability, and its association with adverse outcomes of mortality and hospitalization. DESIGN: Prospective cohort study. SETTING: Single hemodialysis center in Baltimore, Maryland. PARTICIPANTS: One hundred forty-six individuals

undergoing hemodialysis enrolled between January 2009 and March 2010 and followed through August 2012. MEASUREMENTS: Frailty, comorbidity, and disability on enrollment in the study and subsequent mortality and hospitalizations. RESULTS: At enrollment, 50.0% of older (≥ 65) and 35.4% of younger (<65) individuals undergoing hemodialysis were frail; 35.9% and 29.3%, respectively, were intermediately frail. Three-year mortality was 16.2% for nonfrail, 34.4% for intermediately frail, and 40.2% for frail participants. Intermediate frailty and frailty were associated with a 2.7 times (95% confidence interval (CI) = 1.02-7.07, $P = .046$) and 2.6 times (95% CI = 1.04-6.49, $P = .04$) greater risk of death independent of age, sex, comorbidity, and disability. In the year after enrollment, median number of hospitalizations was 1 (interquartile range 0-3). The proportion with two or more hospitalizations was 28.2% for nonfrail, 25.5% for intermediately frail, and 42.6% for frail participants. Although intermediate frailty was not associated with number of hospitalizations (relative risk = 0.76, 95% CI = 0.49-1.16, $P = .21$), frailty was associated with 1.4 times (95% CI = 1.00-2.03, $P = .049$) more hospitalizations independent of age, sex, comorbidity, and disability. The association between frailty and mortality (interaction $P = .64$) and hospitalizations ($P = .14$) did not differ between older and younger participants. CONCLUSIONS: Adults of all ages undergoing hemodialysis have a high prevalence of frailty, more than five times as high as community-dwelling older adults. In this population, regardless of age, frailty is a strong, independent predictor of mortality and number of hospitalizations.

McClellan WM, Anson C, Birkeli K, Tuttle E. **Functional status and quality of life: predictors of early mortality among patients entering treatment for end stage renal disease.** *J Clin Epidemiol.* 1991;44(1):83-9.

Notes: Multicenter observational study of dialysis patients demonstrating association between functional status (based on Karnofsky) and risk of death.

Abstract: We investigated the association between functional status and quality of life in newly-entered dialysis patients and the subsequent risk of mortality. We enrolled the patients from 37 dialysis facilities in two southeastern states ($n = 294$). Functional status was assessed by the Karnofsky Performance Scale (KPS) and quality of life by the Spitzer Quality of Life Index (SQLI). During a mean (SE) follow-up of 479.6 (109.4) days 49 patients (16.4%) of the cohort died. The mean KPS score (SE) for survivors was 7.31 (0.11) and for non-survivors was 5.89 (0.26), P less than 0.0001. The mean SQLI score (SE) for survivors was 6.74 (0.15) and non-survivors was 4.95 (0.28), P less than 0.0001. Strong gradients of the risk of mortality were found for both measurements. After controlling for other covariates including age, race, sex, primary cause of renal failure and the presence of comorbidity, both the KPS and SQLI scores were independently correlated with risk of mortality. We conclude that functional status and quality of life are strong independent risk factors for subsequent mortality in new dialysis patients. These are easily measured indicators which may serve to predict subsequent risk of mortality or adjust case-mix estimates for comparisons between dialysis populations.

*McDougall KA, Larkin JW, Usvyat LA, et al. **Depressive Affect in Incident Hemodialysis Patients is Associated with Increased Hospital Days and Hospital Admissions.** *ASN Expert Abstract #2420 June 2013*

Abstract: "Background: Depression is a key disorder that affects chronic dialysis patients. However, it is not consistently recognized and outcomes related to the disease have not been well-defined, particularly for the first 120 days in incident hemodialysis (iHD) patients. This study investigated the associations between depressive affect (DA) in iHD patients and hospital days/hospital admissions. Methods: Among a random selection of 108 dialysis centers, 429 iHD patients in the first month of chronic outpatient dialysis at FMC NA clinics from Jan-Mar 2013 were identified and telephone contact was attempted for up to three times to administer the Patient Health Questionnaire 2 (PHQ2). The PHQ2 has two questions screening for DA in the previous two weeks. Scores range from 0-6 with a positive DA score defined as ≥ 3 . Hospital admissions and clinical parameters were captured for 120 days after the patients initiated dialysis (up to 30 Apr 2013). Multivariate Poisson regression models were constructed to determine whether hospital days and hospital admissions differ for depressed patients. Results: Among 172 screened iHD patients, DA was detected in 23.3%. Increased hospital days of 15.8 versus (vs) 7.4 days per patient year (ppy) occurred in DA positive vs non-DA patients. Hospital admissions were also greater with 2.9 vs 1.5 events ppy, respectively. Poisson regression identified DA as an independent predictor of hospital days ($p < 0.001$) and a trending predictor of hospital admissions ($p = 0.096$) even after adjustment for covariates typically associated with depression (figure 1). Conclusions: DA in iHD patients was significantly associated with higher hospital days after adjustment for covariates. Further studies are needed to elucidate if interventions that reduce DA improve outcomes."

Sood MM, Rigatto C, Buetti J, et al. **The role of functional status in discharge to assisted care facilities and in-hospital death among dialysis patients.** *Am J Kidney Dis.* 2011 Nov+ADs-58(5):804-12. Epub 2011 Aug 5.

Notes: Retrospective cohort study of hospitalized dialysis pts (n=1286) demonstrating association between ADL score at admission and mortality.

Abstract: BACKGROUND: Functional status is an important component in the assessment of hospitalized patients. We set out to determine the scope, severity, and prognostic significance of impaired functional status in acutely hospitalized dialysis patients. STUDY DESIGN: Retrospective cohort study. SETTING +ACY- PARTICIPANTS: 1,286 hospitalized dialysis patients admitted and discharged from 1 of 11 area hospitals in Manitoba, Canada, from September 2003 to September 2010 with an activity of daily living (ADL) assessment within 24 hours of admission. PREDICTOR: The 12-point ADL score assesses 6 domains (bathing, toileting, dressing, incontinence, feeding, and transferring) and scores them as independent or supervision only (score, 0), partial assistance (1), and full assistance (2). Thus, higher score indicates worse functional status. Parametric and nonparametric tests were used as appropriate to determine differences in baseline characteristics. OUTCOMES: Multivariable logistic regression and Cox proportional hazards assessed the association

between functional status, in-hospital death, and discharge to an assisted care facility. **RESULTS:** During the study period, 250 (19.4+ACU-) and 72 (5.6+ACU-) patients experienced the outcomes of in-hospital death or discharge to an assisted care facility. Abnormalities in functional status were present in +AD4-70+ACU- of the cohort. ADL score within 24 hours of admission combined with age differentiated risks of death and discharge to an assisted care facility home, ranging from 4.8+ACU--46.6+ACU- and 0.6+ACU--17.8+ACU-, respectively. After adjustment, ORs of death and discharge to an assisted care facility were 1.16 (95+ACU- CI, 1.11-1.22+ADs- P +ADw- 0.001+ADs- C statistic +AD0- 0.79) and 1.25 (95+ACU- CI, 1.14-1.36+ADs- P +ADw- 0.001+ADs- C statistic +AD0- 0.91) per 1-point increase in ADL score, respectively. Findings were consistent after accounting for the competing outcomes of in-hospital death or discharge to an assisted care facility versus discharge to home. **LIMITATIONS:** A 1-time measurement of ADLs could not differentiate temporary from long-term deterioration in functional status. **CONCLUSIONS:** Impaired functional status is common at the time of admission in the dialysis population. A single ADL score measurement at admission combined with age is highly predictive of poor outcomes in the hospitalized dialysis population.

Thomas-Hawkins C. **Symptom distress and day-to-day changes in functional status in chronic hemodialysis patients.** *Nephrol Nurs J.* 2000 Aug;27(4):369-79; discussion 380, 428.

Notes: Two center study (n=104) examining daily fluctuations in functional status. Demonstrates variations in functional status pre and post dialysis days, supporting need to specify timing of assessment.

Abstract: The purposes of this study were to examine changes in center-based hemodialysis patients' levels of daily functional status (FS) during the week and to examine the extent to which symptom distress explained variations in daily functional status. A correlational panel study design was used. The sample consisted of 104 chronic incenter hemodialysis patients recruited from two outpatient hemodialysis centers in a mid-Atlantic state. The Inventory of Functional Status was administered daily for 7 consecutive days to assess daily functional status. The Kidney Disease Quality of Life Symptom Scale was administered daily for 7 consecutive days to examine daily symptom distress. Study findings indicated suboptimal levels of FS at baseline, a significant decline in FS the day before the first dialysis session of the week compared to baseline, and a significant decline in FS on the second dialysis day of the week compared to the previous and subsequent nondialysis days. Symptom distress explained 6% of the variation in FS on these 2 days. In conclusion, incenter hemodialysis patients' baseline levels of FS are suboptimal, and FS declines further on the day before the first dialysis session of the week and the second dialysis day of the week. Symptom distress partially accounts for the decline in FS on those days. These findings indicate a need for ongoing FS assessment, implementation of strategies to improve FS, and symptom management in center-based chronic hemodialysis patients.

Burden/Prevalence

Akash N, Ghnaimat M, Haddad A, El-Lozi M. **Functional status of patients on maintenance hemodialysis.** *Saudi J Kidney Dis Transpl.* 1999 Oct-Dec;10(4):481-6.

Notes: Small (n=70) study of two dialysis units examining prevalence of functional status impairment in dialysis patients in Jordan.

Abstract: Factors associated with physical well being were examined in adults with end-stage renal disease (ESRD) in two large hemodialysis units of the Royal Medical Services in Jordan. Utilizing the Karnofski scale we measured the functional status of 200 Patients who had been on maintenance hemodialysis for at least 12 months. A Karnofski scale of less than 70 indicates frank disability (Inability to perform routine living activities without assistance), in addition current vocational status was assessed as well as any existing comorbid conditions. The mean age of the study group was 45.2 years (range 16 to 70) and included 108 (54%) males and 92 (46%) females, there were 39 (19.5%) diabetic patients and 27 (13.5%) patients were receiving erythropoietin (EPO). The mean hematocrit of the entire group was 27.8%. As measured by Karnofski scale, 64 (32%) of the patients were unable to perform routine living activity without assistance; dependence on wheelchair was reported by 9 (4.5%) patients. The mean comorbidity index of patients who scored less than 70 on the Karnofski scale was 1.5 compared to 0.7 for those who scored at least 70 on the same scale ($p < 0.001$). Analysis of factors showed that age and diabetes mellitus affected functional status. Of the laboratory variables measured, only serum albumin concentration correlated significantly with Karnofski scale. Fourteen (21.8%) of the patients who scored below 70, had serum albumin concentration above 40g/L compared to 66 (48.5%) of the patients who scored at least 70 on the Karnofski scale ($p < 0.001$). We conclude that a significant proportion of patients on maintenance hemodialysis is functionally disabled. The elderly, diabetics, patients with high co-morbidity index and those with low serum albumin are most likely to have poor functional status.

*Anand S, Johansen KL, Grimes B, et al. **Physical Activity and Self-reported Symptoms of Insomnia, Restless Legs Syndrome and Depression: the Comprehensive Dialysis Study.** *Hemodialysis international. International Symposium on Home Hemodialysis 2012;17(1):50-58.*

Abstract: Symptoms of sleep and mood disturbances are common among patients on dialysis and are associated with significant decrements in survival and health-related quality of life. We used data from the Comprehensive Dialysis Study (CDS) to examine the association of self-reported physical activity with self-reported symptoms of insomnia, restless legs syndrome (RLS), and depression in patients new to dialysis. The CDS collected data on physical activity, functional status, and health-related quality of life from 1678 patients on either peritoneal (n = 169) or hemodialysis (n = 1509). The Human Activity Profile was used to measure self-reported physical activity. Symptoms were elicited in the following manner: insomnia using three questions designed to capture difficulty in initiating or maintaining sleep, RLS using three questions based on the National Institutes of Health workshop, and depression using the two-item Patient Health Questionnaire. We obtained data on symptoms of insomnia and depression for 1636, and on symptoms of RLS for 1622 (>98%) patients. Of these, 863 (53%) reported one of three insomnia symptoms as occurring at a

persistent frequency. Symptoms of RLS and depression occurred in 477 (29%) and 451 (28%) of patients, respectively. The Adjusted Activity Score of the Human Activity Profile was inversely correlated with all three conditions in models adjusting for demographics, comorbid conditions, and laboratory variables. Sleep and mood disturbances were commonly reported in our large, diverse cohort of patients new to dialysis. Patients who reported lower levels of physical activity were more likely to report symptoms of insomnia, RLS, and depression.

Anderson JE, Kraus J, Sturgeon D. **Incidence, prevalence, and outcomes of end-stage renal disease patients placed in nursing homes.** *Am J Kidney Dis.* 1993 Jun;21(6):619-27.

Abstract: We prospectively surveyed the 156 dialysis centers in Network 5 (MD, VA, WV, DC) for end-stage renal disease (ESRD) patients admitted to or begun on dialysis in nursing homes during a 21-month period (April 1, 1990 to December 31, 1991). In addition to this incidence data, information on patient demographics, social characteristics, pre-existent illnesses, and functional capacity (measured by activity of daily living +AFs-ADL+AF0- scores) was obtained. One hundred thirty-two centers (close to 90+ACU- of Network 5's approximately 9,000 patients) responded to the survey. Outcome data were gathered throughout the 21-month period and the subsequent 5 months. Seventy-three centers dialyzed 228 such patients during the 18-month period. Five centers that were located in the same building as a nursing home cared for 67 patients. The 228 patients, aged 17 to 101 years, were older (65.50 years 14.2 +AFs-SD+AF0- v 53.7 16.4 years), and disproportionately female (62.2+ACU- v 48.3+ACU-), white (46.5+ACU- v 37.4+ACU-), and diabetic (57.9+ACU- v 29+ACU-) compared with the general network ESRD population (P +ADw- 0.05). On admission to the nursing home 47+ACU- of patients had organic heart disease, 35+ACU- had an organic brain syndrome, 22+ACU- had cerebrovascular diseases, 19+ACU- had amputations, and 18+ACU- were blind. The mean admission ADL score was 8.1 5.2 (maximum function, 18) and the patients did not differ regarding age, sex, race, or diabetes. Forty-three percent of patients lived alone or in sheltered housing before being placed in the nursing home.(ABSTRACT TRUNCATED AT 250 WORDS)

Carlson DM, Johnson WJ, Kjellstrand CM. **Functional status of patients with end-stage renal disease.** *Mayo Clin Proc.* 1987 May;62(5):338-44.

Abstract: A longitudinal study of 979 patients with end-stage renal disease from 27 dialysis centers in the Upper Midwest was conducted to measure the patients' functional status with use of the Karnofsky Activity Scale. At the initiation of dialysis, 50% of all patients were rehabilitated or caring for themselves, and the three variables that most influenced the initial rehabilitation score were age, diabetic status, and sex. Initial functional status was also analyzed for three cohorts of dialysis patients, grouped according to outcome (renal transplantation, continued dialysis, and death). Patients who received a renal transplant had initial rehabilitation scores that were higher than those who underwent dialysis for 2 years or those who died. In the group of patients who underwent dialysis for 2 years, a statistically significant improvement in rehabilitation scores was noted at 2

years in comparison with the scores obtained at the initiation of dialysis. Initial rehabilitation scores were good predictors of the 2-year scores. Of the patients in the 2-year dialysis cohort, 78% maintained or had improvement in their functional status.

Cook WL, Jassal SV. **Functional dependencies among the elderly on hemodialysis.** *Kidney Int.* 2008 Jun+Ads-73(11):1289-95. Epub 2008 Mar 19.

Abstract: As the dialysis population ages, their limitations in performing daily activities affect the well-being of the patients as well as increase the burden on caregivers and the use of health services. In this cross-sectional study, we measured the proportion of patients 65 years and older undergoing chronic outpatient hemodialysis who needed help with day-to-day activities and identified the clinical characteristics of this population at most risk. Their dependence in performance of basic self-care tasks and instrumental activities such as driving were measured by the Barthel and Lawton Scales. Associations between disability in four basic activities to age, gender, education, multiple prescription drug needs, diabetes, cognition, depressive symptoms, and physical performance were examined using logistic regression. Of the 162 mostly male participants averaging 75 years old, eight had no disability, 69 had only instrumental dependence, and 85 had combined disability. Multiple prescription drug needs, poor timing in 'up-and-go' mobility performance, and education level were associated with basic dependency. Our study shows that the disability in self-care is common among older patients on hemodialysis. Strategies are needed to routinely identify those older dialysis patients at risk of functional impairment and to limit their disabilities.

Curtin RB, Oberley ET, Sacksteder P, Friedman A. **Differences between employed and nonemployed dialysis patients.** *Am J Kidney Dis.* 1996 Apr;27(4):533-40.

Notes: Cross sectional study (n=359) demonstrating association between employment status and functional status as assessed by SF-20 and Karnofsky scores among chronic dialysis patients.

Abstract: Three hundred fifty-nine chronic dialysis patients (85 employed and 274 nonemployed) were surveyed to identify/verify those characteristics which differentiate between employed versus nonemployed status. Education emerged as a significant correlate of employment, as noted by previous investigators, whereas, unlike previous research, neither mode of dialysis, length of time on dialysis, number of comorbid conditions, nor cause of renal failure (eg, diabetes) were associated with employment status. Measures of functional status (MOS SF-20 and Karnofsky) were positively associated with employment. Furthermore, patients' perceptions that their health limited the type and amount of work that they could do were negatively associated with employment. In addition, using a series of de novo items, we found subjects' beliefs about dialysis patients' ability to work to be a "self-fulfilling prophecy" with regard to employment status. That is, patients who themselves believed that dialysis patients should work and had this notion reinforced by significant others were more likely to be employed. Interestingly, 21 percent of unemployed patients reported that they were both able to work and wanted to return to work. Because it is consistently reported that only a small percentage of dialysis patients are employed, targeting the patients who are both willing and

able to work for vocational rehabilitation might significantly increase the numbers of employed dialysis patients.

Hart LG, Evans RW. **The functional status of ESRD patients as measured by the Sickness Impact Profile.** *J Chronic Dis.* 1987;40 Suppl 1:117S-136S.

Abstract: This study describes and compares the perceived sickness-related behavioral dysfunction of 859 end-stage renal disease (ESRD) patients from 11 centers according to treatment modality via the Sickness Impact Profile (SIP). The unadjusted functional status of ESRD patients differed significantly by treatment modality. Transplantation patients were least functionally limited followed in order by home dialysis, continuous peritoneal dialysis, and in-center dialysis patients. The largest overall differences were for the sleep and rest, work, recreation and pastimes, and home management SIP categories. Regression analysis revealed that many of the large observed intermodality differences in functional status may have resulted from casemix variations (e.g. age and comorbidity differences). Only SIP score differences between transplantation and other treatment modality patients remained significant following the introduction of casemix controls. Results do not justify choosing one dialysis modality over another because of differences in perceived dysfunction.

Ifudu O, Paul H, Mayers JD, et al. **Pervasive failed rehabilitation in center-based maintenance hemodialysis patients.** *Am J Kidney Dis.* 1994 Mar;23(3):394-400.

Abstract: At its inception in 1972, the end-stage renal disease (ESRD) program was conceived with a set of assumptions about cost, rate of growth, and treatment outcomes in its client population. Despite the potential to correct anemia with recombinant erythropoietin (EPO) introduced in 1987 and improved survival, the level of physical activity among some segments of the hemodialysis population remains suboptimal. This study was undertaken, among other reasons, to identify correlates of poor functional status as measured by a modified Karnofsky scale. Using a modified Karnofsky scale, we measured the functional status of 430 patients who had been treated by hemodialysis for at least 1 year and some of whom were also receiving concomitant treatment with EPO. Patients studied were randomly selected from eight dialysis units in urban New York and suburban New Jersey. A Karnofsky score of less than 70 indicated frank disability--the subject was unable to perform routine living chores without assistance. In addition, current vocational activity was ascertained, and comorbid conditions were quantified. The necessity for wheelchair dependence was noted for each patient. The mean age (SD) of the study population was 56 14 years (range, 21 to 92 years). Subjects had been on maintenance hemodialysis for 4.09 3.8 years (range, 1 to 23 years). The study group included 215 men and 215 women, of whom 65% were black, 27% white, 6% Hispanic, and 2% Asian; 36.5% had diabetes mellitus. Although 376 members (87%) of the study group were under treatment with EPO, the mean hematocrit of the study population was only 29% 4.5%. (ABSTRACT TRUNCATED AT 250 WORDS)

Ifudu O, Mayers J, Matthew J, et al. **Dismal rehabilitation in geriatric inner-city hemodialysis patients.** *JAMA.* 1994 Jan 5;271(1):29-33.

Abstract: OBJECTIVE: To assess the extent of functional and vocational rehabilitation achieved by elderly inner-city patients sustained on maintenance hemodialysis. DESIGN: Inception cohort study of elderly patients who have end-stage renal disease using a modified Karnofsky rating system. The need for a wheelchair, participation in household activities, and effect of comorbid conditions were noted. Current status was compared with patient's recollection of functional activity level 2 years before commencing maintenance hemodialysis. SETTING: Seven outpatient, hospital-affiliated and private hemodialysis units in Brooklyn, NY. PATIENTS: One hundred four patients aged 65 years or older who were receiving maintenance hemodialysis for at least 6 months. MAIN OUTCOME MEASURES: A score of 76 or greater on a modified Karnofsky scale indicated independent function at a level that permitted participation in activities beyond those mandated by the hemodialysis regimen. A comorbidity score 6 or greater on a newly constructed index correlated with severe debility. Employment status was also recorded. RESULTS: Present functional activity had deteriorated to a modified Karnofsky score of 66.12.3 (SD) compared with patients' recollection of a mean score of 84.14.3 ($P < .001$) 2 years before initiation of hemodialysis. Diabetic patients had a lower score than nondiabetic patients. The mean comorbidity index of the entire study group was 7.82.9 (mean SD). Within the diabetic subset, severe debility constrained 71 patients (68%) to limit all activity to their residence with the exception of travel to and from their dialysis facility. By contrast, 2 years prior to commencing dialytic therapy, 81 diabetic patients (78%) had interests and activities that took them outside their homes ($P < .001$). Generalized weakness was the most common explanation given for the lack of outside activity by nine patients (9%) who were wheelchair bound. Erythropoietin, though regularly administered to 87 patients (84%) in the study group, was unsuccessful in raising mean hematocrit reading above 0.280.05 (mean SD). CONCLUSIONS: Maintenance hemodialysis does not return inner-city elderly patients to their predialysis level of functioning. Few elderly, diabetic hemodialysis patients conduct any substantive portion of their lives outside their homes. For nondiabetic patients, the modified Karnofsky score of whites (70.411.9) and blacks (66.515.3), though low, was equivalent ($P < .4$).

Johansen KL, Shubert T, Doyle J, et al. **Muscle atrophy in patients receiving hemodialysis: effects on muscle strength, muscle quality, and physical function.** *Kidney Int.* 2003 Jan;63(1):291-7.

Abstract: BACKGROUND: Dialysis patients are less active and have reduced functional capacity compared to individuals with normal renal function. Muscle atrophy and weakness may contribute to these problems. This investigation was undertaken to quantify the extent of atrophy in the lower extremity muscles, to determine whether defects in muscle specific strength (force per unit mass) or central nervous system (CNS) activation are present, and to assess the relationship between muscle size and physical performance in a group of patients on hemodialysis. METHODS: Thirty-eight dialysis subjects (aged 55-15 years) and nineteen healthy sedentary controls (aged 55-13 years) were enrolled. Magnetic resonance imaging of the lower leg was used to determine the total cross-sectional area (CSA) and the area of contractile and non-contractile tissue of the ankle dorsiflexor

muscles. Isometric dorsiflexor strength was measured during a maximal voluntary contraction with and without superimposed tetanic stimulation (N +AD0- 22 for dialysis subjects, N +AD0- 12 for controls). Physical activity was measured by accelerometry, and gait speed was recorded as a measure of physical performance. RESULTS: Dialysis subjects were weaker, less active, and walked more slowly than controls. Total muscle compartment CSA was not significantly different between dialysis subjects and controls, but the contractile CSA was smaller in the dialysis patients even after adjustment for age, gender, and physical activity. Central activation and specific strength were normal. Gait speed was correlated with contractile CSA. CONCLUSIONS: Significant atrophy and increased non-contractile tissue are present in the muscle of patients on hemodialysis. The relationship between contractile area and strength is intact in this population. Muscle atrophy is associated with poor physical performance. Thus, interventions to increase physical activity or otherwise address atrophy may improve performance and quality of life.

Johansen KL, Chertow GM, Kutner NG, et al. **Low level of self-reported physical activity in ambulatory patients new to dialysis.** *Kidney Int.* 2010 Dec;78(11):1164-70. Epub 2010 Sep 1.

Notes: USRDS Comprehensive Dialysis Study (n=1547) of incident dialysis pts describing prevalence of low physical activity.

Abstract: Physical inactivity contributes to the frailty and the decline in function that develops over time among patients with end-stage renal disease. We assessed physical activity among 1547 ambulatory patients new to dialysis in the United States Renal Data System Comprehensive Dialysis Study. We used a self-reporting Human Activity Profile that included Maximal and Adjusted Activity Scores and compared results to established norms by age and gender. Physical activity was found to be extremely low with scores for all age and gender categories below the 5th percentile of healthy individuals and 95% of patients had scores consonant with low fitness. Older age, female gender, diabetes, atherosclerotic disease, and a low level of education were associated with lower activity scores assessed by univariate and multivariable linear regression analysis. Higher serum albumin, creatinine, and lower body mass index, but not hemoglobin levels, were associated with greater physical activity. By multivariable analysis, patients on hemodialysis using a catheter reported lower levels of physical activity compared to those on peritoneal dialysis, hemodialysis using an arteriovenous fistula, or with a graft. Lower Maximal and Adjusted Activity Scores were associated with poor physical function and mental health. Hence, physical activity is distressingly low among patients new to dialysis. Thus, strategies to enhance activity in these patients should be explored.

Kurella Tamura M, Meyer JB, Saxena AB, et al **Prevalence and significance of stroke symptoms among patients receiving maintenance dialysis.** *Neurology.* 2012 Sep 4;79(10):981-7. Epub 2012 Aug 8.

Abstract: OBJECTIVE: The purpose of this cross-sectional study was to determine the prevalence and potential significance of stroke symptoms among end-stage renal disease (ESRD) patients without a prior diagnosis of stroke or TIA. METHODS: We enrolled 148 participants with ESRD from 5 clinics. Stroke symptoms and functional status, basic and instrumental activities of daily living (ADL,

IADL), were ascertained by validated questionnaires. Cognitive function was assessed with a neurocognitive battery. Cognitive impairment was defined as a score 2 SDs below norms for age and education in 2 domains. IADL impairment was defined as needing assistance in at least 1 of 7 IADLs. RESULTS: Among the 126 participants without a prior stroke or TIA, 46 (36.5%) had experienced one or more stroke symptoms. After adjustment for age, sex, race, education, language, diabetes, and cardiovascular disease, participants with stroke symptoms had lower scores on tests of attention, psychomotor speed, and executive function, and more pronounced dependence in IADLs and ADLs ($p \leq 0.01$ for all). After adjustment for age, sex, race, education, language, diabetes, and cardiovascular disease, participants with stroke symptoms had a higher likelihood of cognitive impairment (odds ratio [OR] 2.47, 95% confidence interval [CI] 1.03-5.92) and IADL impairment (OR 3.86, 95% CI 1.60-9.28). CONCLUSIONS: Stroke symptoms are common among patients with ESRD and strongly associated with impairments in cognition and functional status. These findings suggest that clinically significant stroke events may go undiagnosed in this high-risk population.

*Kutner NG et al. **The Comprehensive Dialysis Study: a USRDS special study.** *Found in Chapter 9: Rehabilitation/ quality of life & nutrition special studies, USRDS ADR 2012(2):310*

Abstract: The effort between the Nutrition Special Studies Center (SSC) and the rehabilitation/ Quality of Life SSC, enrolling incident dialysis patients between September 1, 2005, and June 1, 2007 from a stratified random sample of dialysis facilities throughout the U.S. All participants were asked to respond to a patient questionnaire (PQ) by telephone, focusing on physical activity and quality of life, and patients initiating dialysis in a prespecified subset of facilities were also asked to respond to a brief food frequency questionnaire (FFQ) and to provide baseline and quarterly serum samples. A total of 1,678 participants were enrolled from 296 facilities, of whom 399 participated in the nutrition substudy. In this chapter the Rehabilitation/Quality of Life SSC examines early awareness of peritoneal dialysis and transplant as treatment options among CDS participants. The Nutrition SSC then looks at health status among participants, examining data on physical activity, frailty, sleep issues, depression, and dietary intake. These results emphasize a subset of what was collected in the CDS. These data can be used to explore relationships among nutritional intake, markers of nutritional status and inflammation, and physical activity, functioning, symptoms and health-related quality of life. In addition, linkage with the broader USRDS datasets will allow for prospective analyses of the associations of these parameters with outcomes such as hospitalization and survival. Table 9.a lists elements of the patient activity and quality of life questionnaire, Figure 9.1 illustrates the distribution of study participants, and Table 9.b shows their sociodemographic characteristics. CDS participants were slightly younger than the overall population of patients who started dialysis in 2005 and had a slightly greater percentage of patients initiating on peritoneal dialysis (10 percent).

Kutner NG, Zhang R, McClellan WM. **Patient-reported quality of life early in dialysis treatment: effects associated with usual exercise activity.** *Nephrol Nurs J.* 2000 Aug;27(4):357-67; discussion 368, 424.

Notes: Multicenter observational study (n=304) of HD pts associating usual exercise activity levels with physical function.

Abstract: The purpose of this study was to investigate factors associated with quality of life (QoL) early in treatment in a cohort of incident (i.e. newly diagnosed) dialysis patients. This multicenter study investigated QoL reported by patients on chronic hemodialysis (HD) and peritoneal dialysis (PD) at approximately 60 days following the start of treatment. QoL was assessed by the Medical Outcomes Study Short-Form 36 (MOS-SF 36) and by disease-targeted scales from the Kidney Disease Quality of Life (KDQOL). Patient's QoL as measured by the SF-36 was substantially impaired compared to norms for the general population. In univariate analyses, patients' QoL scores were related to demographic variables (age, race, sex, educational level), clinical variables (predialysis BUN and serum creatinine, primary diagnosis of diabetes, cardiovascular comorbidity, average hematocrit and serum albumin in first months of treatment), dialysis variables (HD/PD modality, PD dialysis adequacy, facility patient-staff ratio) and patient's level of usual exercise activity. In multivariate analyses, the most important independent QoL predictor was patient's usual level of exercise activity. Exercise activity independently predicted two performance measures of physical functioning, maximal gait speed and repeated chair rises, as well as patient-perceived physical functioning. Continued study of patient outcomes in relation to adequacy of delivered dialysis, early versus late diagnosis of chronic renal failure (CRF), and patient's usual exercise activity is important because these variables can be the focus for intervention strategies to prevent early deterioration in dialysis patients' functional health status.

Kutner NG, Brogan D, Hall WD, Haber M, Daniels DS. **Functional impairment, depression, and life satisfaction among older hemodialysis patients and age-matched controls: a prospective study.** *Arch Phys Med Rehabil.* 2000 Apr;81(4):453-9.

Abstract: OBJECTIVE: To compare change over time in functional impairment, depression, and life satisfaction among older dialysis patients and age-matched controls. DESIGN: Prospective cohort study over 3 years. SETTING: Urban and rural communities throughout Georgia. SUBJECTS: One hundred thirteen prevalent renal failure patients on in-center hemodialysis and 286 controls. MAIN OUTCOME MEASURES: Ordinal functional impairment index and life satisfaction rating, and Center for Epidemiologic Studies Depression Scale. RESULTS: Dialysis patients, compared with controls, reported significantly more functional impairment at baseline, and also at follow-up after adjusting for baseline impairment and covariates. Dialysis patients had higher depression scores at baseline, and also at follow-up after adjusting for baseline depression and covariates. In contrast, dialysis patients reported lower life satisfaction at baseline than did controls, but the two cohorts were not significantly different on reported life satisfaction at follow-up, after adjusting for baseline life satisfaction and race. In both cohorts, functional impairment and depression were significantly related. CONCLUSION: Older dialysis patients' life satisfaction at a 3-year follow-up, which was similar to life satisfaction among age-matched controls, indicates the value of delivered dialysis care; the value of this care would be increased by reducing excess functional impairment in these patients.

Kutner NG, Johansen KL, Kaysen GA, et al. **The comprehensive dialysis study (CDS): a USRDS special study.** *Clin J Am Soc Nephrol.* 2009 Mar;4(3):645-50. Epub 2009 Mar 4.

Notes: This paper focuses on describing the Comprehensive Dialysis Study (CDS), a potential resource for studies of functional status in the ESRD population.

Abstract: BACKGROUND AND OBJECTIVES: The Comprehensive Dialysis Study (CDS) aimed to understand factors contributing to physical, functional, and nutritional health status among patients starting dialysis. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: A phone interview survey was conducted with patients from a geographically stratified national random sample of dialysis units, and quarterly serum samples were obtained for patients at a preidentified subset of units. The phone survey collected standardized measures of physical activity, employment and disability status, perceived health and well-being, and dietary intake. Serum samples were obtained to measure prealbumin, albumin, creatinine, normalized protein catabolic rate, and C-reactive protein. To comply with restrictions required under the Health Insurance Portability and Accountability Act (HIPAA), dialysis unit personnel could not participate in any research-related activities. RESULTS: Overall participation rate was 18.5%. One thousand six hundred forty-six patients affiliated with 295 dialysis units completed the phone survey; 361 patients affiliated with 68 dialysis units also completed a dietary intake survey, with 269 providing serum samples. Despite challenges in the design and implementation of CDS, the population was diverse and results should be generalizable. CONCLUSIONS: Constraints within the dialysis industry and HIPAA requirements render the assembly of nationally representative cohorts extremely difficult. Nevertheless, the CDS represents the largest cohort of incident dialysis patients containing detailed information on self-reported physical activity and dietary intake and is one of few cohorts simultaneously measuring laboratory proxies of nutrition and inflammatory status. Data from CDS can be used to inform the design of interventions addressing several conditions that affect longevity and health status in ESRD.

Kutner NG, Zhang R, Allman RM, Bowling CB. **Correlates of ADL difficulty in a large hemodialysis cohort.** *Hemodial Int.* 2014 Jan;18(1):70-7. Epub 2013 Oct 9.

Notes: Study in HD pts (n=742) showing association between frailty and functional status as assessed by ADL difficulty.

Abstract: Needing assistance with activities of daily living (ADL) is an early indicator of functional decline and has important implications for individuals' quality of life. However, correlates of need for ADL assistance have received limited attention among patients undergoing maintenance hemodialysis (HD). A multicenter cohort of 742 prevalent HD patients was assessed in 2009-2011 and classified as frail, prefrail and nonfrail by the Fried frailty index (recent unintentional weight loss, reported exhaustion, low grip strength, slow walk speed, low physical activity). Patients reported need for assistance with 4 ADL tasks and identified contributing symptoms/conditions (pain, balance, endurance, weakness, others). Nearly 1 in 5 patients needed assistance with 1 or more ADL. Multivariable analysis showed increased odds for needing ADL assistance among frail

(odds ratio [OR] 11.35; 95% confidence interval [CI] 5.50-23.41; $P < 0.001$) and prefrail (OR 1.93; 95% CI 1.01-3.68; $P = 0.046$) compared with non-frail patients. In addition, the odds for needing ADL assistance were lower among blacks compared with whites and were higher among patients with diabetes, lung disease, and stroke. Balance, weakness, and "other" (frequently dialysis-related) symptoms/conditions were the most frequently named reasons for ADL difficulty. In addition to interventions such as increasing physical activity that might delay or reverse the process of frailty, the immediate symptoms/conditions to which individuals attribute their ADL difficulty may have clinical relevance for developing targeted management and/or treatment approaches.

Mittal SK, Ahern L, Flaster E, et al. **Self-assessed physical and mental function of haemodialysis patients.** *Nephrol Dial Transplant.* 2001 Jul;16(7):1387-94.

Notes: Single center descriptive study (n=134) of physical and mental component scores from SF-36 in HD pts compared to general population and other chronic diseases.

Abstract: BACKGROUND: Physical (PCS) and mental (MCS) component summary scales of the Short Form 36 (SF-36) health survey are validated measures of quality of life (QOL) and functional status. We sought to evaluate the PCS and MCS in haemodialysis patients as compared to the general population and other chronic diseases. METHODS: A cohort of 134 haemodialysis patients (mean age 60.914.3 years, males 63.4%, Caucasians 66.4%) was followed from January 1996 to December 1998 (mean follow up 14.55.7 months). SF-36 questionnaires were administered every 3 months and PCS and MCS were calculated. Results were compared to the general population and other chronic diseases. Correlators of PCS and MCS, change in QOL over time, and the correlators of this change were determined. RESULTS: Mean PCS was 36.98.8 and mean MCS was 4710.7. Compared to the general US population, these represent a decline of 8.70.8 for PCS ($P < 0.0001$) and 2.70.8 for MCS ($P < 0.001$). PCS and MCS in end-stage renal disease (ESRD) were lower than in most other chronic diseases studied. Univariate correlators of PCS in haemodialysis patients included age, male sex, haematocrit, serum albumin, and severity of comorbid cardiac and pulmonary illnesses. Multivariate analysis demonstrated independent correlators of PCS to be male sex, serum albumin and severity of comorbid cardiac and pulmonary diseases. Univariate as well as multivariate correlators of MCS included: serum albumin, KT/V(urea), and status living alone. A trend analysis revealed that both PCS and MCS tended to decline in the initial months of dialysis but stabilized over time. Status living alone was a significant predictor of improvement in MCS by univariate as well as multivariate analysis. CONCLUSIONS: Self assessed physical and mental health of haemodialysis patients is markedly diminished compared to the general population and other chronic diseases.

Murtagh FE, Addington-Hall JM, Higginson IJ. **End-stage renal disease: a new trajectory of functional decline in the last year of life.** *J Am Geriatr Soc.* 2011 Feb;59(2):304-8. Epub 2011 Jan 28.

Notes: Focuses on patients with advanced CKD not managed with dialysis.

Abstract: OBJECTIVES: To determine the functional trajectory in the last year of life in end-stage renal disease managed without dialysis. DESIGN: Longitudinal cohort study of functional status over time and toward death. SETTING: Three renal units in the United Kingdom. PARTICIPANTS: Patients with Stage 5 chronic kidney disease managed conservatively (without dialysis). MEASUREMENTS: The main outcome measure was functional status, measured using the Karnofsky Performance Scale. RESULTS: Seventy-five participants (mean age 80.7, 62% response rate) recruited and followed up monthly for up to 2 years (median 8-month follow-up, range 1-23 months). Forty-nine (66%) died during follow-up. Those who died had similar distribution of age, ethnicity, primary renal pathology, and comorbidity as those still alive at study end. Analysis according to time before death revealed that functional status remained stable during the last year of life but declined steeply in the last month of life. CONCLUSION: This distinctive renal trajectory, reported here for the first time, contrasts with that previously described in other conditions. This has important clinical implications—the steep functional decline indicates that healthcare services need to be rapidly responsive to changing needs in this population as function declines in the last months and weeks of life.

Painter P, Kuskowski M. **A closer look at frailty in ESRD: getting the measure right.** *Hemodial Int.* 2013 Jan;17(1):41-9. Epub 2012 Jun 20.

Notes: A study of dialysis pts (n=188) from the Renal Exercise Demonstration Project correlating physical function (from SF-36) and frailty measures.

Abstract: Patients treated with dialysis have low levels of physical functioning and activity. Whether this translates into frailty or not may depend on how the frailty phenotype is operationalized. This is a secondary analysis of data from the Renal Exercise Demonstration Project to evaluate two methods of operationalizing the Fried phenotype for frailty: Using measured walking speed and muscle weakness (FRAILmeas) and using substitution of the Physical Function Scale (PF) from the SF-36 questionnaire for walking speed and muscle weakness (FRAILsubst). Complete data for both measures were available for 188 hemodialysis patients. The frailty score (FRAILmeas) was the sum of criteria scores for measured gait speed, chair stand, body mass index, vitality, and physical activity. The frailty score (FRAILsubst) substituted the PF scale score (<75) as a surrogate measure for gait speed and for weakness. The frailty score ranged from 0 to 5. Scores ≥ 3 were categorized as frail, and < 3 as not frail. The substitution of the PF score for walking speed and muscle weakness resulted in 78% of patients being categorized as frail compared to 24% using actual measured walking speed and muscle weakness ($P < .001$). The component of frailty that had the highest prevalence was low physical activity (average 54% of subjects). Frailty (using the FRAILmeas) was higher in patients with increasing age, female gender, and lower self-reported PF. Frailty is highly prevalent in hemodialysis patients; however, measured constructs of the components of frailty should be used to report the frailty phenotype.

Rebollo P, Ortega F, Baltar JM, et al. **Health-related quality of life (HRQOL) in end stage renal disease (ESRD) patients over 65 years.** *Geriatr Nephrol Urol.* 1998;8(2):85-94.

Abstract: OBJECTIVES: The aim of the study was to assess Health Related Quality of Life (HRQOL) of elderly patients on renal replacement therapy (RRT) of our region, and to identify socio-demographic and clinical variables which influence it. We also attempted to compare HRQOL of transplant patients, with that of chronic hemodialysis patients. DESIGN: Cross-sectional study. SETTING: Institutional Hospital Nephrology Unit. PATIENTS: All patients from 9 of the 10 hemodialysis centres in our region, aged 65 years or more, who had been on RRT (chronic hemodialysis and kidney transplantation) for at least three months, showing no cognitive problems, were included. The sample included 124 patients. INTERVENTIONS: These patients participated in a structured interview using two generic HRQOL questionnaires: Sickness Impact Profile and SF-36 Health Survey. Karnofsky Scale, Comorbidity Index, socio-demographic and clinical data, were also collected. RESULTS: The median age was 71 years (range 65-75); 55.6% of the patients were male; 19.8% of the sample were transplant patients and 80.2%, hemodialysis patients (only 2% on renal transplant waiting list); 69.2% had a low-intermediate socio-economic level, 52.9% had elementary studies, and 10.6% lived alone. Transplant patients had higher HRQOL than hemodialysis patients. Women had lower HRQOL than men. A higher economic level, higher educational level, higher Karnofsky Performance Scale, and lower Comorbidity Index score, were associated with higher HRQOL. CONCLUSIONS: The good HRQOL of elderly transplant patients, in comparison with hemodialysis patients, is an important reason for advising kidney transplants in elderly patients. Economic and educational levels, functional status and comorbidity are variables which influence the HRQOL of these patients.

Reese PP, Cappola AR, Shults J, et al. **Physical performance and frailty in chronic kidney disease.** *Am J Nephrol.* 2013;38(4):307-15. Epub 2013 Oct 4.

Notes: Study based on CRIC cohort showing associations with reduced eGFR and frailty and poor physical performance.

Abstract: BACKGROUND: Poor physical performance and frailty are associated with elevated risks of death and disability. Chronic kidney disease (CKD) is also strongly associated with these outcomes. The risks of poor physical performance and frailty among CKD patients, however, are not well established. METHODS: We measured the Short Physical Performance Battery (SPPB; a summary test of gait speed, chair raises and balance; range 0-12) and the five elements of frailty among 1,111 Chronic Renal Insufficiency Cohort participants. Adjusting for demographics and multiple comorbidities, we fit a linear regression model for the outcome of SPPB score and an ordinal logistic regression model for frailty status. RESULTS: Median (interquartile range, IQR) age was 65 (57-71) years, median estimated glomerular filtration rate (eGFR) for non-dialysis patients was 49 (36-62) ml/min/1.73 m², and median SPPB score was 9 (7-10). Seven percent of participants were frail and 43% were pre-frail. Compared with the SPPB score for eGFR >60 ml/min/1.73 m², the SPPB was 0.51 points lower for eGFR 30-59; 0.61 points lower for eGFR 15-29, and 1.75 points lower for eGFR <15 (p < 0.01 for all comparisons). eGFR 30-59 (odds ratio, OR 1.45; p = 0.024), eGFR 15-29 (OR 2.02; p = 0.002) and eGFR <15 (OR 4.83; p < 0.001) were associated with worse frailty status compared with eGFR >60 ml/min/1.73 m². CONCLUSIONS: CKD severity was associated with poor physical

performance and frailty in a graded fashion. Future trials should determine if outcomes for CKD patients with frailty and poor physical performance are improved by targeted interventions.

Roshanravan B, Khatri M, Robinson-Cohen C, et al. **A prospective study of frailty in nephrology-referred patients with CKD.** *Am J Kidney Dis.* 2012 Dec;60(6):912-21. Epub 2012 Jul 7.

Notes: Observational cohort study (n=336) of non-dialysis CKD patients demonstrating association between frailty and risk of death or progression to ESRD.

Abstract: BACKGROUND: Frailty is a construct developed to characterize a state of reduced functional capacity in older adults. However, there are limited data describing the prevalence or consequences of frailty in middle-aged patients with chronic kidney disease (CKD). STUDY DESIGN: Observational study. SETTING & PARTICIPANTS: 336 non-dialysis-dependent patients with stages 1-4 CKD with estimated glomerular filtration rate (eGFR) <90 mL/min/1.73 m² (by the CKD-EPI [CKD Epidemiology Collaboration] serum creatinine-based equation) or evidence of microalbuminuria enrolled in the Seattle Kidney Study, a clinic-based cohort study. Findings were compared with community-dwelling older adults in the Cardiovascular Health Study. OUTCOME: Prevalence and determinants of frailty in addition to its association with the combined outcome of all-cause mortality or renal replacement therapy. MEASUREMENTS: We defined frailty according to established criteria as 3 or more of the following characteristics: slow gait, weakness, unintentional weight loss, exhaustion, and low physical activity. We estimated kidney function using serum cystatin C concentrations (eGFR(cys)) to minimize confounding due to relationships of serum creatinine levels with muscle mass and frailty. RESULTS: The mean age of the study population was 59 years and mean eGFR(cys) was 51 mL/min/1.73 m². The prevalence of frailty (14.0%) was twice that of the much older non-CKD reference population (P < 0.01). The most common frailty components were physical inactivity and exhaustion. After adjustment including diabetes, eGFR(cys) categories of <30 and 30-44 mL/min/1.73 m² were associated with a 2.8- (95% CI, 1.3-6.3) and 2.1 (95% CI, 1.0-4.7)-fold greater prevalence of frailty compared with GFR(cys) ≥60 mL/min/1.73 m². There were 63 events during a median 987 days of follow-up. After adjustment, the frailty phenotype was associated with an estimated 2.5 (95% CI, 1.4-4.4)-fold greater risk of death or dialysis therapy. LIMITATIONS: Cross-sectional study design obscures inference regarding temporal relationships between CKD and frailty. CONCLUSIONS: Frailty is relatively common in middle-aged patients with CKD and is associated with lower eGFR(cys) and increased risk of death or dialysis therapy.

Sclauzero P, Galli G, Barbati G, Carraro M, Panzetta GO. **Role of components of frailty on quality of life in dialysis patients: a cross-sectional study.** *J Ren Care.* 2013 Jun;39(2):96-102. Epub 2013 May 14.

Notes: Italian study (n=203) demonstrating association between frailty and quality of life in dialysis pts.

Abstract: BACKGROUND: Many people on dialysis suffer a variety of conditions that can affect frailty (the condition or quality of being frail), such as comorbidities, disabilities, dependence, malnutrition, cognitive impairment and poor social conditions. Frailty is suspected to affect quality of life (QoL). OBJECTIVES: The study aimed to evaluate the effect of the different components of frailty on the QoL of people on dialysis. METHODS: We enrolled 203 out of 233 prevalent patients on dialysis in the Trieste area of Italy. We applied the Short-Form 36 (SF-36) questionnaire, Activities of Daily Living, Instrumental Activities of Daily Living, Subjective Global Assessment scales and Karnofsky Index. In addition we analysed their social conditions. RESULTS: Dependence, malnutrition and disability had a negative role on QoL. Living with family and good social-economic conditions were significantly related to a better QoL. CONCLUSIONS: Dependence, malnutrition, disability, poor social and economic conditions have a significant effect on life quality. The role of comorbidities appears to be less important. Screening of patients, nutritional and functional rehabilitation and prevention of social isolation appear to be indispensable in guaranteeing a satisfactory life quality.

Development and Validation of Instruments

Farrokhi F, Jassal SV. **Routine use of an abbreviated 4-item scale to assess dependence in essential activities of daily living amongst elderly hemodialysis patients: a validation study.** *Int Urol Nephrol.* 2013 Feb;45(1):259-64. Epub 2013 Jan 1.

Notes: Single center study of 167 pts validating a proposed brief 4 item instrument, with comparison to the Barthel Index.

Abstract: BACKGROUND: Poor functional status is associated with reduced survival and poor outcomes in older dialysis patients. The Geriatric Nephrology Advisory Group recommends routine evaluation of functional status on all older patients; however, assessments can be time consuming and burdensome to clinical care providers. The objective of this study was to validate an abbreviated 4-item self-report screening tool for use in elderly hemodialysis patients. METHODS: The functional dependence of community-dwelling hemodialysis patients, aged ≥ 65 years, was measured by trained evaluators. The accuracy of a 4-item self-report activities of daily living (ADL) score was compared against formal evaluation by the Barthel Index and the outcomes using agreement statistics and Cox regression analysis. RESULTS: The cohort included 167 patients with a mean age of 74.8 \pm 5.9 years (57 % males). The 4-item scale correctly identified 83 % of the patients dependent in ≥ 1 ADL. Those incorrectly identified as independent on the abbreviated scale were uniformly unable to climb stairs without assistance. The sensitivity and specificity, and coefficient for agreement between the 4-item scale and the Barthel Index were 83.2, 100 and 0.78 %, respectively. The positive and negative predictive values of the 4-item scale were 100 and 76.9 %, respectively. Using the 4-item scale, the presence of severe disability was predictive of increased mortality (HR 12.5; 95 % CI 2.5-65.0; P = 0.03). CONCLUSIONS: The 4-item scale is a simple, valid screening test for disability which can be used in the elderly population on dialysis as a screening tool. Difficulties with stair climbing may be overlooked using this score.

Kurtin PS, Davies AR, Meyer KB, et al. **Patient-based health status measures in outpatient dialysis. Early experiences in developing an outcomes assessment program.** *Med Care.* 1992 May;30(5 Suppl):MS136-49.

Notes: Qualitative study examining practical issues with administration of SF-36 in dialysis facilities.

Abstract: This paper describes the initial development of a patient-based outcomes assessment program in an outpatient dialysis unit. This project presented four logistical and practical issues that are discussed in this paper: patient acceptance of quarterly administrations of a generic health status survey (the SF-36); timing of administration during dialysis session; respondent burden; and staff burden. Also discussed are three issues related to the clinical use of these assessments: medical record status of SF-36 data; use in clinical decisionmaking; and clinicians' responses to aggregate data from patient-based health status assessments. The investigation reported presents strong evidence of patient acceptance of the SF-36. Data collection problems reflected the nature of a busy dialysis unit, and most have been corrected. Considering functional status, the role functioning of dialysis patients is most adversely affected; among well-being measures, patients are most compromised by pain and lack of energy. Clinicians' reviews of these results point to the need for normative data, information about severity of primary and comorbid diseases, and knowledge of relationships between SF-36 scores and physiologic parameters to make clinical use of generic health outcome assessments.

*Lattanzio F, Corsonello A, Abbatecola AM, Volpato S, Pedone C, Pranno L, Laino I, Garasto S, Corica F, Passarino G, Antonelli Incalzi R. **Relationship between renal function and physical performance in elderly hospitalized patients.** *Rejuvenation Res.* 2012 Dec;15(6):545-52. doi: 10.1089/rej.2012.1329. Epub 2012 Sep 24.

Abstract: Chronic kidney disease (CKD) is increasingly recognized as a cause of worsening physical functioning in older patients. The Short Physical Performance Battery (SPPB) is highly reliable in older populations, but no data on older hospitalized patients with different degrees of kidney function are available. We aimed at testing the association between estimated glomerular filtration rate (eGFR) and SPPB, either global score (range 0-12) or its individual components (muscle strength, balance, and walking speed, each ranging from 0 to 4), in a sample of older hospitalized patients. Our series consisted of 486 patients aged 65 or more consecutively enrolled in 11 acute care medical wards participating to a multicenter observational study. eGFR was obtained by the Chronic Kidney Disease Epidemiological Collaboration (CKD-EPI) equation. Physical performance was objectively measured by the SPPB. The relationship between eGFR and SPPB was investigated by multiple linear regression analysis. Physically impaired patients (SPPB total score < 5) were older, had lower serum albumin and Mini-Mental State Examination (MMSE) scores as well as higher overall co-morbidity, prevalence of stroke, cancer, and anemia compared to those with intermediate (SPPB=5-8) and good physical performance (SPPB=9-12). Fully adjusted multivariate models showed that eGFR (modeled as 10 mL/min per 1.73 m² intervals) was independently associated with the SPPB total score (B=0.49; 95% confidence interval [CI]=0.18-0.66; p=0.003), balance (B=0.30; 95% CI=0.10-0.49; p=0.005), and muscle strength (B=0.06; 95% CI=0.01-0.10; p=0.043), but not with

walking speed ($B=-0.04$; 95% CI= $-0.09-0.11$; $p=0.107$). In conclusion, reduced renal function is associated with poorer physical performance in older hospitalized patients. SPPB is worthy of testing to monitor changes in physical performance in elderly CKD patients.

Mercer TH, Naish PF, Gleeson NP, Wilcock JE, Crawford C. **Development of a walking test for the assessment of functional capacity in non-anaemic maintenance dialysis patients.** *Nephrol Dial Transplant.* 1998 Aug+ADs-13(8):2023-6.

Notes: Validation study of a walking-stair-climbing task for assessment of functional capacity as assessed by peak VO₂.

Abstract: BACKGROUND: Walk tests may be useful adjuncts or even alternatives to the assessment of peak oxygen uptake (VO₂ peak) in patients with low functional capacity. Walk tests are easy to administer, appear to be well tolerated by patients and may represent a more meaningful measure for a patient group as they assess capability as well as fitness. However, the use of walk tests for the assessment of functional capacity in maintenance dialysis patients has received scant attention. The aim of this study was to assess the validity of a walking-stair-climbing test to predict VO₂ peak in non-anaemic maintenance dialysis patients. METHODS: In the validation phase of the study, 14 subjects completed a cycle ergometer-graded exercise test (GXT) for the determination of VO₂ peak and a walking-stair-climbing task (WALK), each separated by a period of 7 days. Three weeks later, 18 subjects completed two WALK tests, each separated by a period of at least 48 h, to facilitate reliability estimation. Estimates of differentiated and undifferentiated ratings of perceived exertion (RPE) were obtained during and immediately consequent to all exercise tests. RESULTS: VO₂ peak (ml kg min) was significantly correlated with total WALK time (s) ($r+AD0- -0.83+ADs- P +ADw- 0.001$). VO₂ peak (ml/kg/min) could be predicted from total WALK time with a standard error of prediction of 11+ACU-. Reliability assessment revealed no significant differences for any aspect of the WALK test performance, with intraclass correlation coefficients ranging from $r+AD0- 0.71$ (RPElegs) to 0.96 (total WALK time). CONCLUSION: These results indicate that the WALK test is a valid, reliable and potentially useful method by which to assess the functional capacity of non-anaemic maintenance dialysis patients.

Saito GK, Jassal SV. **The 'Sit-to-Scale' score--a pilot study to develop an easily applied score to follow functional status in elderly dialysis patients.** *Nephrol Dial Transplant.* 2007 Nov;22(11):3318-21. Epub 2007 Jul 4.

Notes: Single center study (n=30) of HD patients who had undergone inpatient rehabilitation, validating the sit-to-scale score as an instrument for documenting changes in functional status.

Abstract: AB- not available

Soangra R, Lockhart TE, Lach J, Abdel-Rahman EM. **Effects of hemodialysis therapy on sit-to-walk characteristics in end stage renal disease patients.** *Ann Biomed Eng.* 2013 Apr;41(4):795-805. Epub 2012 Dec 5.

Notes: Very small (n=6) study suggesting impact of dialysis session may be important - in this case, sit-to-walk activity was slower following the dialysis session. This information may be relevant with respect to timing of physical assessments of functional status.

Abstract: Patients with end stage renal diseases (ESRD) undergoing hemodialysis (HD) have high morbidity and mortality due to multiple causes; one of which is dramatically higher fall rates than the general population. In spite of the multiple efforts aiming to decrease the high mortality and improve quality of life in ESRD patients, limited success has been achieved. If adequate interventions for fall prevention are to be achieved, the functional and mobility mechanisms consistent with falls in this population must be understood. Human movements such as sit-to-walk (STW) tasks are clinically significant, and analysis of these movements provides a meaningful evaluation of postural and locomotor performance in elderly patients with functional limitations indicative of fall risks. In order to assess the effects of HD therapy on fall risks, 22 sessions of both pre- and post-HD measurements were obtained in six ESRD patients utilizing customized inertial measurement units (IMU). IMU signals were denoised using ensemble empirical mode decomposition and Savitzky-Golay filtering methods to detect relevant events for identification of STW phases. The results indicated that patients were slower to get out of the chair (as measured by trunk flexion angular accelerations, time to peak trunk flexion, and overall STW completion time) following the dialysis therapy session. STW is a frequent movement in activities of daily living, and HD therapy may influence the postural and locomotor control of these movements. The analysis of STW movement may assist in not only assessing a patient's physical status, but in identifying HD-related fall risk as well. This preliminary study presents a non-invasive method of kinematic measurement for early detection of increased fall risk in ESRD patients using portable inertial sensors for out-patient monitoring. This can be helpful in understanding the pathogenesis better, and improve awareness in health care providers in targeting interventions to identify individuals at risk for fall.

Takken T, Engelbert R, van Bergen M, et al. **Six-minute walking test in children with ESRD: discrimination validity and construct validity.** *Pediatr Nephrol.* 2009 Nov;ADs-24(11):2217-23. Epub 2009 Jul 25.

Notes: Small (n=20) study examining validity of six minute walk assessment in children on dialysis. One of the few studies focusing on pediatric population.

Abstract: The six-minute walking test (6MWT) may be a practical test for the evaluation functional exercise capacity in children with end-stage renal disease (ESRD). The aim of this study was to investigate the 6MWT performance in children with ESRD compared to reference values obtained in healthy children and, secondly, to study the relationship between 6MWT performance with anthropometric variables, clinical parameters, aerobic capacity and muscle strength. Twenty patients (13 boys and seven girls+ADs- mean age 14.1 ± 3.4 years) on dialysis participated in this

study. Anthropometrics were taken in a standardized manner. The 6MWT was performed in a 20-m-long track in a straight hallway. Aerobic fitness was measured using a cycle ergometer test to determine peak oxygen uptake ($V O_{2peak}$), peak rate (W_{peak}) and ventilatory threshold (VT). Muscle strength was measured using hand-held myometry. Children with ESRD showed a reduced 6MWT performance (83+ACU- of predicted, $p < 0.0001$), irrespective of the reference values used. The strongest predictors of 6MWT performance were haematocrit and height. Regression models explained 59+ACU- (haematocrit and height) to 60+ACU- (haematocrit) of the variance in 6MWT performance. 6MWT performance was not associated with $V O_{2peak}$, strength, or other anthropometric variables, but it was significantly associated with haematocrit and height. Children with ESRD scored lower on the 6MWT than healthy children. Based on these results, the 6MWT may be a useful instrument for monitoring clinical status in children with ESRD, however it cannot substitute for other fitness tests, such as a progressive exercise test to measure $V O_{2peak}$ or muscle strength tests.

Thomas-Hawkins C, Fawcett J, Tulman L. **The Inventory of Functional Status-Dialysis: development and testing.** *ANNA J.* 1998 Oct;25(5):483-90.

Notes: Validation of the Inventory of Functional Status - Dialysis (IFS-Dialysis).

Abstract: OBJECTIVE: Development and psychometric testing of the Inventory of Functional Status-Dialysis (IFS-Dialysis), which was designed to measure functional status in persons who are receiving chronic incenter hemodialysis treatment. DESIGN: Three-phase instrument development design: Phase 1--content validity assessment; Phase 2--examination of internal consistency reliability; Phase 3--examination of construct validity. SAMPLE/SETTING: 175 chronic hemodialysis patients recruited from an urban, free-standing, outpatient dialysis center. METHODS: Content validity was determined using Popham's average congruency procedure. Internal consistency reliability was determined using Cronbach's alpha reliability coefficient. Construct validity was examined by bivariate correlations between the IFS-Dialysis and the Karnofsky Performance Scale (KPS), and the Medical Outcomes Study Short Form-36 Health Survey (SF-36) in a subsample of 60 patients. RESULTS: Content validity was established at 90%. The alpha reliability coefficient for the IFS-Dialysis was 0.86. Subscale alpha coefficients ranged from 0.71-0.82. Correlation between the IFS-Dialysis and the KPS was 0.55. Correlations between the IFS-Dialysis and SF-36 subscales ranged from 0.14-0.53. CONCLUSIONS: The IFS-Dialysis has acceptable content validity, internal consistency, and initial construct validity. Use of the IFS-Dialysis in clinical practice is appropriate.

*Watnick, Suzanne, Wang, Pei-Li, Demadura, Theresa, Ganzini, Linda. **Validation of 2 Depression Screening Tools in Dialysis Patients.** *AJKD, Vol 46, No 5 (November), 2005: pp 919-924*

Abstract: Background: Depression is the most common psychiatric disorder in long-term dialysis patients and is a risk factor for morbidity and mortality. An efficient and valid method of diagnosing depression might facilitate recognition and treatment. We sought to validate 2 depression assessment tools, the 21-question Beck Depression Inventory (BDI) and the 9-question Patient

Health Questionnaire (PHQ-9), in a dialysis population. Methods: We surveyed patients who had received dialysis for at least 90 days in Portland, OR. We excluded patients with dementia, delirium, or a history of major psychiatric disorders other than depression. The Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, a gold-standard measure for depression, was administered by trained psychologists within 2 weeks of the BDI and PHQ-9. Results: Of 62 enrolled subjects, 16 were diagnosed with a depressive disorder, including 12 patients (19%) with major depression, 3 patients with dysthymia, and 1 patient with minor depression. Optimal BDI and PHQ-9 cutoff values for depressive disorders combined was 16 or greater and 10 or greater, respectively. Sensitivities were 91% and 92%, specificities were 86% and 92%, positive predictive values were 59% and 71%, and negative predictive values were both 98%, with κ values of 0.65 and 0.75, respectively. The difference between the 2 receiver operating characteristic curves was not statistically significant ($P > 0.9$). Conclusion: Our results validate the PHQ-9 and revalidate the BDI against a gold-standard measure for depressive disorders in the dialysis population. Both tools performed equally well. Because depression is prevalent, readily diagnosed, and associated with poor outcomes, screening by means of short and valid measurement tools may lead to better diagnosis and treatment of this modifiable risk factor. This may lead to improved clinical outcomes in dialysis patients.

Interventions

Beusterien KM, Nissenson AR, Port FK, et al. **The effects of recombinant human erythropoietin on functional health and well-being in chronic dialysis patients.** *J Am Soc Nephrol.* 1996 May;7(5):763-73.

Notes: Open-label multicenter study (n=484) of effects of erythropoietin on SF-36 scores in dialysis patients.

Abstract: As a component of the open-label, multicenter National Cooperative Recombinant Human Erythropoietin (Epo) Study, the health-related quality-of-life effects of Epo therapy were assessed in 484 dialysis patients who had not previously been treated with Epo therapy (New-to-Epo) and 520 dialysis patients who were already receiving Epo therapy at the time of study enrollment (Old-to-Epo). Using scales from the Medical Outcomes Study 36-item Short Form Health Survey (SF-36), health-related quality of life was assessed on study enrollment (baseline) and at an average of 99 days follow-up. At baseline, SF-36 scores for Old- and New-to-Epo patients were well below those observed in the general population, reflecting substantial impairments in functional status and well-being among patients with chronic renal failure. Significant improvements from baseline to follow-up were observed among New-to-Epo patients in vitality, physical functioning, social functioning, mental health, looking after the home, social life, hobbies, and satisfaction with sexual activity ($P < 0.05$ for each). The mean improvements in hematocrit values among New-to-Epo and Old-to-Epo patients were 4.6 and 0.3, respectively. At the time of follow-up, SF-36 scores for New-to-Epo patients were comparable with those observed among Old-to-Epo patients, whose scores did not change significantly from baseline to follow-up. Analysis of the relationship between

Epo therapy, hematocrit values, and health-related quality of life suggest that some of the beneficial quality-of-life effects of Epo are mediated through a change in hematocrit level.

Brass EP, Adler S, Sietsema KE, et al. **Intravenous L-carnitine increases plasma carnitine, reduces fatigue, and may preserve exercise capacity in hemodialysis patients.** *Am J Kidney Dis.* 2001 May;37(5):1018-28.

Notes: Report of two RCTs of intravenous L-carnitine in HD pts; showed some improvement in fatigue score on Kidney Disease Questionnaire.

Abstract: Exercise capacity in patients with end-stage renal disease (ESRD) remains impaired despite correction of anemia. Carnitine insufficiency may contribute to impaired exercise and functional capacities in patients with ESRD. Two randomized placebo-controlled trials were conducted to test whether intravenous L-carnitine improves exercise capacity (assessed by maximal rate of oxygen consumption +AFs-VO(2max)+AF0-) and quality of life (measured by the Kidney Disease Questionnaire +AFs-KDQ+AF0-) in patients with ESRD. In study A, patients were administered L-carnitine, 20 mg/kg (n +AD0- 28), or placebo (n +AD0- 28) intravenously at the conclusion of each thrice-weekly dialysis session for 24 weeks. In study B, a dose-ranging study, patients were administered intravenous L-carnitine, 10 mg/kg (n +AD0- 32), 20 mg/kg (n +AD0- 30), or 40 mg/kg (n +AD0- 32), or placebo (n +AD0- 33) as in study A. The prospective primary statistical analysis evaluated changes in VO(2max) in each study and specified that changes in the KDQ were assessed only in the combined populations. L-Carnitine supplementation increased plasma carnitine concentrations, but did not affect VO(2max) in either study. Because change in VO(2max) showed significant heterogeneity, a secondary analysis using a mixture of linear models approach on the combined study populations was performed. L-Carnitine therapy (combined all doses) was associated with a statistically significant smaller deterioration in VO(2max) (-0.88 0.26 versus -0.05 0.19 mL/kg/min, placebo versus L-carnitine, respectively+ADs- P +AD0- 0.009). L-Carnitine significantly improved the fatigue domain of the KDQ after 12 (P +AD0- 0.01) and 24 weeks (P +AD0- 0.03) of treatment compared with placebo using the primary analysis but did not significantly affect the total score (P +AD0- 0.10) or other domains of the instrument (P +AD4- 0.11). Carnitine was well tolerated, and no drug-related adverse effects were identified. Intravenous L-carnitine treatment increased plasma carnitine concentrations, improved patient-assessed fatigue, and may prevent the decline in peak exercise capacity in hemodialysis patients. VO(2max) in the primary analysis and other assessed end points were unaffected by carnitine therapy.

Castaneda C, Gordon PL, Parker RC, et al. **Resistance training to reduce the malnutrition-inflammation complex syndrome of chronic kidney disease.** *Am J Kidney Dis.* 2004 Apr;43(4):607-16.

Notes: Small single center RCT (unblinded) in patients with moderate CKD. Intervention was resistance training and outcomes included evaluation of changes in lab measures of inflammation (CRP and Il-6) as well as muscle histology. Relevant in that it provides additional information about

clinical lab correlates of improved functional status in patients with CKD. One limitation is that the study population was not inclusive of advanced CKD-ND or CKD-D groups.

Abstract: BACKGROUND: Systemic inflammation and protein-energy malnutrition may be associated with poor outcomes in kidney disease. METHODS: We studied 26 adults (age, 65 10 [SD] years) with chronic kidney disease, not on dialysis therapy. Subjects were randomly assigned to resistance training (n = 14) or a control group (n = 12) for 12 weeks, while counseled to consume a low-protein diet (protein, approximately 0.6 g/kg/d). We determined whether resistance training reduces levels of inflammatory mediators (serum C-reactive protein [CRP] and interleukin-6 [IL-6]), in addition to previously reported improvements in nutritional and functional status in this same subject population. RESULTS: Serum CRP levels were reduced in subjects undergoing resistance training (-1.7 mg/L) compared with controls (1.5 mg/L; P = 0.05). Similarly, IL-6 levels were reduced in the resistance-exercise group versus controls (-4.2 versus 2.3 pg/mL; P = 0.01). Resistance training lead to skeletal muscle hypertrophy, shown by increases in type I (24% 31%) and type II (22% 41%) muscle fiber cross-sectional areas, compared with control subjects (-14% 34% and -13% 18%, respectively; P < 0.05). Muscle strength also improved with resistance training (28% 14%) compared with controls (-13% 22%; P = 0.001). CONCLUSION: Resistance training reduced inflammation and improved nutritional status in individuals with moderate chronic kidney disease consuming a low-protein diet. These results need to be investigated further in larger cohorts of patients with varying stages of kidney disease to determine whether resistance training can improve disease outcomes long term.

Chen JL, Godfrey S, Ng TT, et al. **Effect of intra-dialytic, low-intensity strength training on functional capacity in adult haemodialysis patients: a randomized pilot trial.** *Nephrol Dial Transplant.* 2010 Jun+ADs-25(6):1936-43. Epub 2010 Jan 25.

Notes: Small (n=50) unblinded two-center trial of intra-dialytic low intensity exercise among HD pts. Showed improvement in physical performance as measured by Short Physical Performance Battery score as compared to control (stretching exercises).

Abstract: BACKGROUND: Kidney failure is associated with muscle wasting and physical impairment. Moderate- to high-intensity strength training improves physical performance, nutritional status and quality of life in people with chronic kidney disease and in dialysis patients. However, the effect of low-intensity strength training has not been well documented, thus representing the objective of this pilot study. METHODS: Fifty participants (mean SD, age 69 13 years) receiving long-term haemodialysis (3.7 4.2 years) were randomized to intra-dialytic low-intensity strength training or stretching (attention-control) exercises twice weekly for a total of 48 exercise sessions. The primary study outcome was physical performance assessed by the Short Physical Performance Battery score (SPPB) after 36 sessions, if available, or carried forward from 24 sessions. Secondary outcomes included lower body strength, body composition and quality of life. Measurements were obtained at baseline and at completion of 24 (mid), 36 (post) and 48 (final) exercise sessions. RESULTS: Baseline median (IQR) SPPB score was 6.0 (5.0), with 57+ACU- of the participants having SPPB scores below 7.

Exercise adherence was 89.15%+ACU-. The primary outcome could be computed in 44 participants. SPPB improved in the strength training group compared to the attention-control group +AFs- 21.1+ACU- (43.1+ACU-) vs. 0.2+ACU- (38.4+ACU-), respectively, P = 0.03+AF0-. Similarly, strength training participants exhibited significant improvements from baseline compared to the control group in knee extensor strength, leisure-time physical activity and self-reported physical function and activities of daily living (ADL) disability+ADs- all P = 0.02. Adverse events were common but not related to study participation. CONCLUSIONS: Intra-dialytic, low-intensity progressive strength training was safe and effective among maintenance dialysis patients. Further studies are needed to establish the generalizability of this strength training program in dialysis patients.

Evans RW, Rader B, Manninen DL. **The quality of life of hemodialysis recipients treated with recombinant human erythropoietin. Cooperative Multicenter EPO Clinical Trial Group.** *JAMA.* 1990 Feb 9;263(6):825-30.

Abstract: Initial clinical trials with recombinant human erythropoietin provided evidence of a quality-of-life benefit for patients with anemic end-stage renal disease who received maintenance hemodialysis. As part of a phase III clinical trial of recombinant human erythropoietin, the quality of life of patients was systematically assessed. More than 300 patients at nine dialysis centers were evaluated. A statistically significant improvement was established between baseline and second follow-up on most objective and subjective quality-of-life parameters, including energy and activity level, functional ability, sleep and eating behavior, disease symptoms, health status, satisfaction with health, sex life, well-being, psychological affect, life satisfaction, and happiness. No change was observed in ability to work or employment status. We conclude that, in addition to substantial improvement in hematologic parameters, recombinant human erythropoietin greatly enhances the quality of life of anemic patients who receive maintenance hemodialysis.

*Hall YN, Larive B, Painter P, Kaysen GA, Lindsay RM, Nissenson AR, Unruh ML, Rocco MV, Chertow GM; Frequent Hemodialysis Network Trial Group. **Effects of six versus three times per week hemodialysis on physical performance, health, and functioning: Frequent Hemodialysis Network (FHN) randomized trials.** *Clin J Am Soc Nephrol.* 2012 May;7(5):782-94. doi: 10.2215/CJN.10601011. Epub 2012 Mar 15.

Abstract: BACKGROUND AND OBJECTIVES: Relatively little is known about the effects of hemodialysis frequency on the disability of patients with ESRD. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: This study examined changes in physical performance and self-reported physical health and functioning among subjects randomized to frequent (six times per week) compared with conventional (three times per week) hemodialysis in both the Frequent Hemodialysis Network daily (n=245) and nocturnal (n=87) trials. The main outcome measures were adjusted change in scores over 12 months on the short physical performance battery (SPPB), RAND 36-item health survey physical health composite (PHC), and physical functioning subscale (PF) based on the intention to treat principle. RESULTS: Overall scores for SPPB, PHC, and PF were poor relative to population norms and in line with other studies in ESRD. In the Daily Trial, subjects randomized to frequent compared with conventional in-center hemodialysis experienced no significant change in SPPB

(adjusted mean change of -0.20 ± 0.19 versus -0.41 ± 0.21 , $P=0.45$) but experienced significant improvement in PHC (3.4 ± 0.8 versus 0.4 ± 0.8 , $P=0.009$) and a relatively large change in PF that did not reach statistical significance. In the Nocturnal Trial, there were no significant differences among subjects randomized to frequent compared with conventional hemodialysis in SPPB (adjusted mean change of -0.92 ± 0.44 versus -0.41 ± 0.43 , $P=0.41$), PHC (2.7 ± 1.4 versus 2.1 ± 1.5 , $P=0.75$), or PF (-3.1 ± 3.5 versus 1.1 ± 3.6 , $P=0.40$). **CONCLUSIONS:** Frequent in-center hemodialysis compared with conventional in-center hemodialysis improved self-reported physical health and functioning but had no significant effect on objective physical performance. There were no significant effects of frequent nocturnal hemodialysis on the same physical metrics.

Headley S, Germain M, Mailloux P, et al. **Resistance training improves strength and functional measures in patients with end-stage renal disease.** *Am J Kidney Dis.* 2002 Aug;40(2):355-64.

Notes: Uncontrolled study of resistance training of HD pts ($n=10$) showed improvements in functional ability, as assessed by six minute walk.

Abstract: **BACKGROUND:** The current study was designed to examine the effect of 12 weeks of resistance training on strength and functional ability in 10 medically stable hemodialysis patients (age, 42.8 ± 4.4 years). **METHODS:** Subjects were tested on four separate occasions, each separated by 6 weeks. The first (T1) and second tests (T2) were controls with no exercise intervention between them. T3 followed 6 weeks of resistance training, and T4 occurred after 12 weeks of training. Variables tested included percentage of body fat, distance covered in the 6-minute walk test, peak torque of quadriceps muscles of the dominant leg, maximal handgrip strength, normal and maximal walking speeds, and time to complete 10 repetitions of the sit-to-stand-to-sit test. Data were analyzed by means of a one-way repeated-measures analysis of variance procedure. **RESULTS:** Results indicate that after 12 weeks of training, there was a significant ($P < 0.05$) increase (12.7 ± 18.7 ACU) in peak torque at 90 degrees /s (139.1 ± 19.3 nm) compared with T1 and T2 (mean, 124.1 ± 18.7 AFs-SEM+AF0AOw- 123.5 ± 16.9 Nm), respectively. The distance covered during the 6-minute walk was increased (approximately 5 ± 46.2 ACUAOW- $P < 0.05$) compared with baseline (T1, 522.1 ± 46.2 m+ADs- 521.9 ± 48.5 m) after 6 weeks of training (548.3 ± 52.1 m) and remained elevated at week 12 (546.5 ± 54.2 m). Maximal walking speed was increased ($P < 0.05$) by week 12 (195.9 ± 15.4 cm/s) compared with baseline (T1, 182.9 ± 12.7 ADs- 185.5 ± 13.0 cm/s). Time to complete 10 repetitions of the sit-to-stand-to-sit test decreased at 12 weeks (17.8 ± 1.9 seconds) versus baseline (T1, 20.3 ± 1.5 seconds+ADs- T2, 20.6 ± 5.5 seconds). **CONCLUSION:** Resistance training can be used safely to increase strength and functional capacity in stable hemodialysis patients.

Johansen KL, Mulligan K, Schambelan M. **Anabolic effects of nandrolone decanoate in patients receiving dialysis: a randomized controlled trial.** *JAMA.* 1999 Apr 14;281(14):1275-81.

Notes: Small placebo controlled RCT ($n=29$) of the effect of nandrolone (an anabolic steroid) in dialysis pts on lean body mass and functional status (as assessed by treadmill, walking and stair-climbing).

Abstract: CONTEXT: Patients receiving dialysis commonly experience malnutrition, reduced muscle mass (sarcopenia), and fatigue for which no effective treatment has been identified. Anabolic steroids are known to increase muscle mass and strength in healthy individuals, but their effect on the sarcopenia and fatigue associated with long-term dialysis has not been evaluated. OBJECTIVE: To assess the effects of an anabolic steroid, nandrolone decanoate, on lean body mass (LBM), functional status, and quality of life in dialysis patients. DESIGN: Randomized, double-blind, placebo-controlled trial conducted between April 1996 and July 1997. SETTING: Hospital-based outpatient dialysis unit. PATIENTS: Twenty-nine patients undergoing dialysis for at least 3 months. INTERVENTION: Nandrolone decanoate, 100 mg (n = 14), or placebo (n = 15) by intramuscular injection once a week for 6 months. MAIN OUTCOME MEASURES: Weight, LBM, fatigue, grip strength, walking and stair-climbing times, and treadmill performance after 3 and 6 months of treatment. RESULTS: Lean body mass increased significantly in patients given nandrolone compared with patients given placebo (mean change [SD], .5 [2.3] kg; $P < .001$ compared with baseline). This effect was significantly greater than the change in LBM in the placebo group (mean change [SD], .9 [1.6] kg; $P = .003$ compared with baseline; $P = .005$ compared with nandrolone group). Serum creatinine levels increased in the nandrolone group (? [203] mmol/L [1.9 [2.3] mg/dL]; $P = .02$) but not in the placebo group (-4.0 [177] mmol/L [0.04 [2.0] mg/dL]; $P = .95$), suggesting an increase in muscle mass. Time to complete the walking and stair-climbing test decreased from 36.5 to 32.7 seconds in the nandrolone group, while those in the placebo group increased from 38.7 to 42.1 seconds ($P = .05$). Peak oxygen consumption increased in the individuals in the nandrolone group who performed treadmill tests, but not to a statistically significant degree. Grip strength did not change in either group. CONCLUSIONS: Treatment with nandrolone for 6 months resulted in a significant increase in LBM associated with functional improvement in patients undergoing dialysis.

Konstantinidou E, Koukouvou G, Kouidi E, Deligiannis A, Tourkantonis A. **Exercise training in patients with end-stage renal disease on hemodialysis: comparison of three rehabilitation programs.** *J Rehabil Med.* 2002 Jan;34(1):40-5.

Notes: Single center (n=48) study of three exercise regimens (randomly assigned) or control, on physical fitness parameters in dialysis patients.

Abstract: Functional capacity of end-stage renal disease patients is dramatically impaired. Although exercise training programs appear to have beneficial morphological, functional and psychosocial effects in end-stage renal disease patients on hemodialysis (HD), the adherence rate is high. The purpose of this study was to compare the effects of three modes of exercise training on aerobic capacity and to identify the most favourable, efficient and preferable to patients on HD with regard to functional improvements and participation rate in the programs. Fifty-eight volunteer patients were screened for low-risk status and selected from the dialysis population. The 48 patients who completed the study protocol were randomly assigned either to one of the three training groups or to a control group. Sixteen of them (Group A - mean age 46.413.9 years) completed a 6-month supervised outpatient exercise renal rehabilitation program consisting of three weekly sessions of aerobic and strengthening training on the non-dialysis days; 10 (Group B - mean age 48.312.1 years)

completed a 6-month exercise program during HD; 10 (Group C - mean age 51.412.5 years) followed an unsupervised moderate exercise program at home, and 12 patients (Group D-mean age 50.27.9 years) were used as patient controls. The level of anemia, the medications and the HD prescription remained stable during the study. Fifteen sex- and age-matched sedentary individuals (Group E - mean age 46.96.4 years) comprised a healthy control group for baseline data. All subjects at the beginning and end of the study underwent clinical examination, laboratory tests and a treadmill exercise test to fatigue endpoints with direct measurement of aerobic capacity. Group A had a higher dropout rate (24%) compared to groups B (17%) and C (17%). Peak oxygen consumption (VO₂ peak) increased by 43% ($p < 0.05$), anaerobic threshold (VO₂AT) by 37% ($p < 0.05$) and exercise time by 33% ($p < 0.05$) after training in Group A; by 24% ($p < 0.05$), 18% ($p < 0.05$) and 22% ($p < 0.05$), respectively, in B; and by 17% ($p < 0.05$), 8% ($p < 0.05$) and 14% ($p < 0.05$), respectively, in C; while both remained almost unchanged in Group D. These results demonstrate that intense exercise training on non-dialysis days is the most effective way of training, whereas exercise during HD is also effective and preferable.

Koufaki P, Mercer TH, Naish PF. **Effects of exercise training on aerobic and functional capacity of end-stage renal disease patients.** *Clin Physiol Funct Imaging.* 2002 Mar+ADs-22(2):115-24.

Notes: RCT of exercise program in dialysis pts demonstrated increased peak exercise capacity as assessed by VO₂ measurement.

Abstract: The aim was to assess the effects of exercise training on aerobic and functional capacity of patients with end-stage renal disease (ESRD). Patients completed an incremental exercise test on a cycle ergometer to determine VO₂ peak and VO₂ at ventilatory threshold (VT+ADs- V-slope). On a separate day they performed two constant load exercise tests on a cycle ergometer at 90+ACU- of VT and at a workload of 33 W, to determine VO₂ kinetics. Functional capacity was assessed using measurements of sit-to-stands (STS-5, STS-60) and a walk test. Dialysis patients were randomly allocated to an exercise (ET: n +AD0- 18, age +AD0- 57.3 years) or control (C: n +AD0- 15, age +AD0- 50.5 - 5 years) group. The ET group participated in an exercise training programme involving cycling for 3 months. Repeated measures ANOVA revealed significant time by group interactions ($P +ADw- 0.05$) following training for VO₂ peak (ET: 17 6.1 versus 19.9 6-3, C: 19.5 4.7 versus 188 4.9 ml kg min(-1)) and VO₂-VT (ET: 10.7 3.5 versus 11.8 3.3, C:12.9 3.2 versus 119 3.5 ml kg min(-10)). VO₂ kinetics remained unchanged in both groups at 90+ACU- -VT, but a trend ($P +AD0- 0.059$) towards faster kinetics at the 33 W was observed (ET: 49.6 19.5 versus 37.8 12.7, C: 42.8 13 versus 49.4 20.2 s). Significant time by group interactions ($P +ADw- 0.05$) were also observed for STS-5 (ET: 14.7 6.2 versus 11.0 3.3, C: 12.8 4.4 versus 12.7 4.8 s) and STS-60 measurements (ET: 21.2 7.2 versus 26.9 6.2, C: 23.7 6.8 versus 24.1 7.2). Three months of exercise rehabilitation significantly improves peak exercise capacity of patients with ESRD. Measurements of VO₂ kinetics and functional capacity suggest that longer time might be needed to induce peripheral adaptations.

Kouidi E, Albani M, Natsis K, et al. **The effects of exercise training on muscle atrophy in haemodialysis patients.** *Nephrol Dial Transplant.* 1998 Mar+ADs-13(3):685-99.

Abstract: BACKGROUND: Patients with end-stage renal disease on haemodialysis (HD) have limited work capacity. Many structural and functional alterations in skeletal muscles contribute to this disability. METHODS: To evaluate the effects of exercise training on uraemic myopathy, seven HD patients (mean age 44.117.2 years) were studied. Open muscle biopsies were taken from their vastus lateralis muscle before and after a 6-month exercise rehabilitation programme and examined by routine light- and transmission electron-microscopy. Histochemical stainings of frozen sections were performed and morphometric analysis was also applied to estimate the proportion of each fibre type and the muscle fibre area. Spiroergometric and neurophysiological testing and peak extension forces of the lower limbs were measured before and after exercise training. RESULTS: All patients showed impaired exercise capacity, which was associated with marked muscular atrophy (mean area 2548463 microm²) and reduction in muscle strength and nerve conduction velocity. All types of fibres were atrophied, but type II were more affected. The ultrastructural study showed severe degenerative changes in skeletal muscle fibres, mitochondria, and capillaries. Exercise training had an impressive effect on muscular atrophy+ADs- in particular the proportion of type II fibres increased by 51+ACU- and mean muscle fibre area by 29+ACU-. Favourable changes were also seen on the structure and number of capillaries and mitochondria. These results were confirmed by a 48+ACU- increase in VO₂ peak and a 29+ACU- in exercise time, as well as an improvement in the peak muscle strength of the lower limbs and in nerve conduction velocity. CONCLUSIONS: Skeletal muscle atrophy in HD patients contribute to their poor exercise tolerance. The application of an exercise training rehabilitation programme improved muscle atrophy markedly, and therefore had beneficial effects in overall work performance.

Kouidi E, Grekas D, Deligiannis A, Tourkantonis A. **Outcomes of long-term exercise training in dialysis patients: comparison of two training programs.** *Clin Nephrol.* 2004 May+ADs-61 Suppl 1:S31-8.

Notes: Single center study (n=48) comparing two modes of exercise (exercise on non-dialysis days versus stationary bike during dialysis) on physical fitness.

Abstract: BACKGROUND: Exercise training has been shown to improve the low functional capacity and quality of life in dialysis (HD) patients. However, there are no data about the outcome of long-term exercise training and, also, the adherence of HD patients in such long-term renal rehabilitation programs. Therefore, the aim of this study was to evaluate the effects of 2 modes of long-term physical training on HD patients' physical fitness, perception of health and overall life situation. PATIENTS AND METHODS: Forty-eight HD patients, free of any other systemic disease, who followed 2 modes of exercise training for 4 years, were studied. Half of them (group A) were randomly assigned to participate in a supervised outpatient exercise training program (3/weekly) on the non-dialysis days, while the other half (group B) followed a training program with stationary bicycles during their HD sessions (3/weekly). The measured domains of physical fitness and well-being every year were: aerobic capacity, as estimated from a modified Bruce treadmill exercise test and spiroergometric study, the patients' perception of health, the overall life situation and the employment status. RESULTS: During the 4-year study, there were 8 drop-outs in group A and 5 in B.

No adverse effects of the exercise programs were reported. The 1 year of exercise training resulted in 38+ACU- in group A (16 patients, who remained in the study) and 31+ACU- in group B (18 patients) improvement of exercise time, and a 47+ACU- increase in group A of peak oxygen consumption (VO₂peak) and a 36+ACU- in group B in comparison to baseline value. After 3 additional years of training, significant improvements were also noted in exercise time (by 53+ACU- in group A and by 43+ACU- in B) and VO₂peak (by 70+ACU- in group A and by 50+ACU- in group B), as well as in other gas exchange variables in comparison to baseline values. However, the improvements in group A were more pronounced than in B. Interestingly, the gains in exercise capacity were more enhanced in the first year of training in both groups. After 4-year training, significantly more patients in both groups perceived their health and overall life situation as well, compared to baseline. In addition, perception of improved health was higher in group A. The increase in the proportion of patients working was also higher in group A than B after the 4-year training. CONCLUSION: HD patients can adhere to long-term physical training programs on the non-dialysis days, as well as during hemodialysis with considerable improvements in physical fitness and health. Although training out of HD seems to result in better outcomes, the drop out rate was higher.

Laupacis A, Wong C, Churchill D. **The use of generic and specific quality-of-life measures in hemodialysis patients treated with erythropoietin. The Canadian Erythropoietin Study Group.** *Control Clin Trials.* 1991 Aug+ADs-12(4 Suppl):168S-179S.

Notes: RCT of EPO in HD pts (n=118) showed improvement in exercise stress test performance but not six minute walk.

Abstract: The effect of recombinant human erythropoietin (EPO) on the quality of life and exercise capacity of 118 hemodialysis patients was assessed in a randomized, double-masked placebo-controlled trial. Patients were randomized into three groups: 1) placebo, 2) EPO to achieve a hemoglobin of 95-110 g/L and 3) EPO to achieve a hemoglobin of 115-130 g/L. Patients were followed for six months. Quality of life was assessed using a disease-specific measure +AFs-the Kidney Disease Questionnaire (KDQ)+AF0- and two generic measures +AFs-Sickness Impact Profile (SIP) and the Time Trade OFF (TTO)+AF0-. The KDQ contains five dimensions. Functional capacity was assessed with a Six-Minute Walk test (SMW) and an Exercise Stress Test (EST). The mean hemoglobin at six months was 74, 102, and 117 gm/l in groups one, two and three, respectively. There was a marked improvement in quality of life with EPO therapy, but no difference between groups 2 and 3. The outcome measure that was the most responsive to change was the KDQ (P less than .001 for the fatigue and physical symptoms dimensions). The aggregate global (P less than .02) and physical (P +AD0- .005) scores of the SIP improved with EPO therapy, the psychosocial score did not. There was no improvement in the TTO. There was an improvement in the EST (P +AD0- .02) but not in the SMW. The reproducibility of the outcome measures in placebo-treated patients varied between 0.80 and 0.98 (intra-class correlation coefficient). The correlation among the outcome measures at six months was statistically significant in most cases, as was the correlation of change scores between baseline and six months.

Levendoglu F, Altintepe L, Okudan N, et al. **A twelve week exercise program improves the psychological status, quality of life and work capacity in hemodialysis patients.** *J Nephrol.* 2004 Nov-Dec+ADs-17(6):826-32.

Notes: Single center, uncontrolled study of 12 week exercise program on various aspects of functional status in pts on HD.

Abstract: BACKGROUND: Patients with chronic renal failure (CRF) are restricted in physical, emotional and social dimensions of life due to their treatment and their comorbid medical conditions. We aimed to evaluate the effects of a 12-week exercise program on the functional capacity, functional mobility, walking capacity, quality of life and depression in patients with renal failure on hemodialysis (HD). METHODS: Twenty patients with renal failure on HD were included and 14 of them completed the study. The patients went through a 12-week exercise program of 90 min/day, 3 days a week. Exercise and walking capacity, functional mobility, psychological status and quality of life were evaluated pre- and post-training. RESULTS: Following the exercise, peak oxygen consumption, exercise duration and peak workload improved significantly (respectively, p+AD0-0.006, p+AD0-0.002 and p+AD0-0.002). There were significant improvements in the sit-to-stand-to-sit test and the 6- min walk test (p+ADw-0.001 and p+AD0-0.002). There was a significant reduction in the depression score (p+ADw-0.001). Both physical component scale (PCS) and mental component scale (MCS) of the Kidney Disease Quality of Life Short-Form 36 (SF-36) questionnaire showed significant increases (respectively, p+AD0-0.002 and p+AD0-0.004). CONCLUSION: The application of an appropriate exercise program would improve psychological status and quality of life, as well as work capacity in long-term maintenance HD patients.

Ling KW, Wong FS, Chan WK, et al. **Effect of a home exercise program based on tai chi in patients with end-stage renal disease.** *Perit Dial Int.* 2003 Dec+ADs-23 Suppl 2:S99-S103.

Notes: Uncontrolled study of home-based exercise program for dialysis pts, showing improvement in various measures of functional status such as six minute walk, time up and go. High (>50%) drop out rate.

Abstract: OBJECTIVE: Previous reports have documented the benefits of exercise on the well-being of renal patients. However, fewer than 50+ACU- of our end-stage renal disease (ESRD) patients engage in regular exercise. To promote exercise, we implemented a home-based exercise program. The aim of the program was to reduce barriers to exercise by helping patients to exercise at their convenience and without the need to travel. The effect of the program was evaluated 3 months after implementation. Patients and METHODS: Each study participant received a videotape that demonstrated 30 minutes of low-capacity aerobic exercise. Participants were advised to exercise by following the demonstration on the videotape. Encouragement was given over the telephone. Self-reports on practice were recorded in a log book that was also provided. The effect of the program was evaluated by comparing outcomes data before, and 3 months after, implementation of the

program. Outcomes assessment included functional mobility (timed +ACI-Up +ACY- Go+ACI- test), muscle flexibility (+ACI-Sit +ACY- Reach+ACI- test), physical capacity (+ACI-Six-Minute Walk+ACI-), and quality of life +AFs-Kidney Disease Quality of Life Short Form (KDQOL-SF)+AF0-. RESULTS: The program began with 72 participants. Over time, 39 dropped out. The remaining 33 participants included 11 men and 22 women with a mean age of 52.8 9.8 years. They exercised 3 - 7 times weekly. Significant improvements were observed in the timed +ACI-Up +ACY- Go+ACI- (p +AD0- 0.003) and +ACI-Sit +ACY- Reach+ACI- (p +ADw- 0.001) tests. Improvements in the +ACI-Six-Minute Walk+ACI- (p +AD0- 0.130) and in KDQOL-SF scores for emotional well-being (p +AD0- 0.456), pain (p +AD0- 0.100), burden of kidney disease (p +AD0- 0.061), and general health (p +AD0- 0.085) were statistically insignificant. CONCLUSIONS: Physically, patients with ESRD benefit from home-based low-capacity aerobic exercise. A home-based program provides an alternative to outdoor and group exercise. In view of a high drop-out rate, intensive promotion and encouragement should be considered to achieve a positive outcome.

Malagoni AM, Catizone L, Mandini S, et al. **Acute and long-term effects of an exercise program for dialysis patients prescribed in hospital and performed at home.** *J Nephrol.* 2008 Nov-Dec+ADs-21(6):871-8.

Notes: Non-randomized study (n=31) of exercise program on physical function and quality of life in dialysis pts.

Abstract: BACKGROUND: Exercise has positive psychophysical effects on dialysis patients, thus effective programs should be identified. We evaluated the effects of an original 6-month walking program on physical capacity, health-related quality of life (HRQL) and postdialysis fatigue (PDF). METHODS: Thirty-one dialysis patients (19 male, mean age 65 -/ 11 years) were divided into exercise (group E+ADs- n+AD0-17) and control (group C+ADs- n+AD0-14) groups, and evaluated upon entry, after the 6-month program and 19 -/ 3 months later. Outcome measures were 6-minute walking distance (6MWD), SF-36 scale scores, self-reported PDF and recovery time. E group was assigned 2 daily 10-minute home walking sessions on the nondialysis day at a speed 50+ACU- below maximal treadmill speed as determined and updated monthly at the hospital. C group: no exercise. RESULTS: Twenty patients (13 from E, 7 from C) completed the study. The E group, unlike the C group, increased 6MWD (308 -/ 105 m, to 351 -/ 118 m, p+AD0-0.0007), and HRQL, significantly for bodily pain, physical role and mental health (p+ADw-0.05), decreased PDF and recovery time (p+ADw-0.05). At the follow-up, 15 patients were reevaluated (9 from E, 6 from C). The E group was still active and showed 6MWD similar to baseline, with a decline of 0.13 -/ 1.72 m/mo. The C group decreased 6MWD (p+AD0-0.026) with a decline of 3.43 -/ 3.2 m/mo. For both groups, HRQL, PDF and recovery time showed slight variations from baseline. CONCLUSIONS: In dialysis patients, a 6-month exercise program prescribed at the hospital and performed at home improved physical capacity, HRQL and PDF symptoms. Patients maintained an active lifestyle after discharge and showed a slow functional decline over a 2-year period.

Oh-Park M, Fast A, Gopal S, et al. **Exercise for the dialyzed: aerobic and strength training during hemodialysis.** *Am J Phys Med Rehabil.* 2002 Nov;81(11):814-21.

Notes: Single center study (n=22), uncontrolled, of exercise during dialysis session impact on fitness and physical function.

Abstract: OBJECTIVE: To investigate the safety and feasibility of aerobic and strength training during hemodialysis for end-stage renal disease patients and to evaluate its impact on their cardiac fitness, muscle strength, and functional status. DESIGN: A total of 22 patients undergoing hemodialysis for end-stage renal disease had assessment of their cardiac fitness with stress tests and walk tests, assessment of their muscle strength by one repetition maximum of knee extension, and assessment of their functional status by Medical Outcomes Study Short Form-36 before and after exercise training. Training, consisting of cycle ergometer exercise and strengthening of the knee extensors two to three times a week for 3 mo, was done during dialysis. RESULTS: Eighteen of 22 patients completed 3 mo of training and four dropped out due to knee pain or medical complications unrelated to exercise. No patient developed major complications from the program. After training, there was a significant improvement in the mental and physical components of the Short Form-36 and one repetition maximum of knee extension. Among 14 of 18 patients who agreed and completed a follow-up fitness testing, five showed improvement on the stress tests and eight on the walk tests. CONCLUSIONS: A well designed exercise program during hemodialysis can be performed safely with proper supervision and patient education, improving muscle strength, mental and physical function, and possibly cardiac fitness.

Pellizzaro CO, Thomé FS, Veronese FV. **Effect of peripheral and respiratory muscle training on the functional capacity of hemodialysis patients.** *Ren Fail.* 2013+ADs-35(2):189-97. Epub 2012 Nov 30.

Notes: Small RCT of respiratory muscle training or peripheral muscle training or control (n=39) in HD pts showing improved functional capacity as assessed by six minute walk.

Abstract: Patients on hemodialysis (HD) show changes in muscle structure and function reducing their functional capacity. This study was conducted to assess the effects of respiratory muscle training (RMT) and peripheral muscle training (PMT) during dialysis on functional parameters, inflammatory state, and quality of life (QoL) in patients on HD. Randomized controlled trial included 39 patients on HD, and they were divided into three groups: RMT (n +AD0- 11), PMT (n +AD0- 14), and controls (C, n +AD0- 14). Training was performed during the HD session for 10 weeks. Maximal inspiratory pressure (PI(max)), maximal expiratory pressure (PE(max)), forced vital capacity (FVC), six-minute walk test (6MWT), Kt/V(sp), biochemical parameters, and inflammatory state (i.e., level of high sensitivity C-reactive protein) were evaluated. Variation from baseline was calculated by Analysis of Covariance (ANCOVA). The DeltaPI(max) was 22.5 3.2, 9.1 2.9, and -4.9 2.8 cmH(2)O in the RMT, PMT and C, respectively (p +ADw- 0.001)+ADs- DeltaPE(max) was 10.8 6.6, 3.7 5.9, and -15.6 5.9 cmH(2)O respectively (p +AD0- 0.014). The Delta6MWT was significantly greater in RMT and PMT (65.5 9+ADs- 30.8 8 m) than in C (-0.5 8.1 m), p +ADw- 0.001. Although biochemical

parameters decreased after training, Kt/V remained unchanged. CRP decreased only in the RMT and PMT groups. There was a significant increase in QoL scores in the training groups (vs. C) in energy/fatigue (p +AD0- 0.002), sleep (p +ADw- 0.001), pain (p +ADw- 0.001), and list of symptoms/problems (p +AD0- 0.014). A short period of RMT or PMT during HD significantly improved functional capacity, with RMT showing greater effect than PMT. Muscle training improved biochemical and inflammatory markers, but a direct cause and effect relationship could not be established by this study.

Silva VG, Amaral C, Monteiro MB, et al. **Effects of inspiratory muscle training in hemodialysis patients.** *J Bras Nefrol.* 2011 Mar+ADs-33(1):62-8.

Notes: Uncontrolled trial of HD pts (n=15) showing improvement in six minute walk following inspiratory muscle training.

Abstract: INTRODUCTION: Chronic kidney disease associated with hemodialysis can have a variety of musculoskeletal complications, in addition to repercussions in pulmonary function. OBJECTIVE: To evaluate the effects of inspiratory muscle training on inspiratory muscle strength, pulmonary function, and functional capacity in patients with chronic kidney failure undergoing hemodialysis. METHOD: Non-controlled clinical trial, comprising 15 individuals diagnosed with chronic kidney failure and undergoing hemodialysis. Maximum inspiratory (P_{Imax}) and expiratory (P_{E_{max}}) pressures were assessed by use of pressure vacuum meter reading. Pulmonary function was assessed by use of spirometry. Functional capacity was assessed by use of walked distance and oxygen consumption obtained in the six-minute walk test (6MWT). For eight weeks, the inspiratory muscle training (IMT) protocol was applied during hemodialysis sessions, with load set to 40%ACU- of P_{Imax} and weekly frequency of three alternate days. RESULTS: A significant increase in the walked distance was observed after training (455.5 ± 98 versus 557.8 ± 121.0+ADs- p +AD0- 0.003). No statistically significant difference was observed in the other variables when comparing their pre- and posttraining values. CONCLUSION: The study showed no statistically significant difference in respiratory muscle strength, pulmonary function, and oxygen consumption. An increase in the walked distance was observed in the 6MWT.

Reviews

Brenner, Ingrid **Exercise performance by hemodialysis patients: a review of the literature.** *Phys Sportsmed.* 2009 Dec+ADs-37(4):84-96.

Notes: Qualitative review of effect of exercise in dialysis patients.

Abstract: Hemodialysis (HD) patients exhibit poor functional capacity and reduced quality of life as a result of the complications associated with end-stage renal disease (ESRD). A review of the literature indicates that regular physical activity can reduce the complications associated with ESRD by inducing adaptations in the cardiovascular, nervous, and musculoskeletal systems. In turn, this

increases functional capacity and enhances quality of life in patients on HD. Hemodialysis patients can safely participate in a variety of exercise programs with minimal adverse effects. Intradialytic exercise programs that can incorporate aerobic and resistance exercise promote exercise adherence and should be encouraged on dialysis units.

Brown EA, Johansson L. **Old age and frailty in the dialysis population.** *J Nephrol.* 2010 Sep-Oct;23(5):502-7.

Notes: Qualitative review of frailty and other aspects contributing to functional status.

Abstract: Dialysis management is changing over time due to the changing dialysis population, with many overlapping issues between gerontological and nephrological care. The conditions that are focused on in this review are frailty, cognitive impairment, depression and changes in body composition. These factors should be considered when managing older patients on dialysis.

Cornelis T, Kotanko P, Goffin E, et al. **Can intensive hemodialysis prevent loss of functionality in the elderly ESRD patient?** *Semin Dial.* 2011 Nov-Dec;24(6):645-52. Epub 2011 Nov 29.

Notes: Qualitative review of potential impact of dialysis therapy itself on preservation or decline in functional status.

Abstract: Initiation of dialysis may be accompanied by decline in physical and cognitive function and independence, especially in the elderly ESRD patient. Here, we postulate the underlying factors, which may contribute to this observation in the elderly dialysis population, such as increased risk of dialysis-induced hypotension and associated cerebral and cardiac events, as well as malnutrition, infections, sleep abnormalities, and psychological complications of dialysis initiation. We describe an elderly dialysis patient who did well on nocturnal home hemodialysis (HD), and we hypothesize how intensive HD (i.e., nocturnal HD and/or short daily HD) may reduce the incidence of these dialysis complications and may therefore be considered as an option to attempt to preserve functional status and quality of life, especially early after the transition from predialysis to dialysis. Before general adoption of this strategy, further studies on the etiology of functional loss at the time of dialysis initiation, as well as on the potential advantageous effects of intensive HD in the elderly ESRD patient as compared with conventional HD, peritoneal dialysis and kidney transplantation, are required.

Curtin RB, Lowrie EG, DeOreo PB. **Self-reported functional status: an important predictor of health outcomes among end-stage renal disease patients.** *Adv Ren Replace Ther.* 1999 Apr;6(2):133-40.

Notes: Qualitative review of importance of monitoring functional status in dialysis patients, with specific attention to patient self-report.

Abstract: A contemporary focus on outcomes assessment has provided affirmation that patient functional status is both an important outcome of medical care and an important predictor of longer term outcomes such as morbidity and/or mortality. Monitoring functional status among end-stage renal disease (ESRD) patients is particularly critical because the cycle of physical deconditioning experienced by renal patients is both insidious and malignant. Over the past several years, patient self-report instruments have been used with increasing frequency to assess functioning. Among ESRD patients, such self-reports have reliably predicted mortality and some morbidity. Additionally, renal patients' self-reported functioning is also correlated with the results of several commonly performed laboratory tests. Based on these findings, measures of self-reported functional status might be considered a practical adjunct to regular patient assessments. They could be routinely used for purposes that might include: identifying the particular areas of functioning and well-being that need improvement; screening for subtle changes in health status; establishing physical status baselines; and corroborating the effectiveness of physical activity interventions. Overall, ESRD patients' self-report of their functioning appears to secure, synthesize, and standardize data about patient health status that is unavailable through any other mechanism. Such information may be essential to medicine's primary missions of promoting health and preserving life.

Hall RK, O'Hare AM, Anderson RA, Colón-Emeric CS. **End-stage renal disease in nursing homes: a systematic review.** *J Am Med Dir Assoc.* 2013 Apr;14(4):242-7. Epub 2013 Feb 1.

Notes: Recent systematic review focusing on dialysis patients who are also nursing home residents. Describes prevalence and associated outcomes of functional impairment within that group.

Abstract: OBJECTIVES/INTRODUCTION: Demand for nursing home (NH) care by patients with end-stage renal disease (ESRD) is likely to increase with growing numbers of older adults initiating chronic dialysis. We completed a systematic review to summarize the literature on NH residents with ESRD. METHODS: MEDLINE, CINAHL, EMBASE, and relevant conference proceedings were searched to identify articles using the following MESH terms or related key words in the title or abstract: "residential facilities", "renal dialysis", "renal replacement therapy", and "chronic kidney failure". We selected case control, cohort studies, and clinical trials that included older adults with ESRD (defined as those receiving chronic dialysis or those with stage 5 chronic kidney disease) living in residential care facilities. We abstracted information on study design, quality, and results. RESULTS: Of 198 unique citations identified by the search strategy, 14 articles met eligibility criteria. Most articles were multicenter studies that were conducted in the 1990 s. One study focused on patients with stage 5 chronic kidney disease, and the remaining 13 studies focused on patients receiving chronic dialysis, of which eight studies included only those receiving peritoneal dialysis, four studies included patients receiving both peritoneal dialysis and hemodialysis, and one study included only patients receiving hemodialysis. All studies were observational, no clinical trials were identified, and study design limitations and heterogeneity within study populations were common. Summarizing results across these studies suggests that NH residents with ESRD have limited survival, particularly early after dialysis initiation. Functional impairment is highly prevalent in this population and independently associated with poor outcomes. CONCLUSIONS: NH residents with ESRD appear

to be a particularly vulnerable population, but current information on their prevalence, characteristics, and outcomes is limited. Further research is needed to provide a better understanding of modifiable predictors of survival and functional decline in this population.

Jassal SV, Chiu E, Li M. **Geriatric hemodialysis rehabilitation care.** *Adv Chronic Kidney Dis.* 2008 Apr;15(2):115-22.

Notes: Systematic review of prevalence of functional status impairment, and impact of rehabilitation in dialysis patients.

Abstract: The 2 objectives of this review are to provide background information about functional status in older dialysis patients and to discuss the utility of geriatric dialysis rehabilitation. We performed a literature search using PubMed and MedLine. All relevant texts were reviewed for information on functional status and disability in the renal population and in the general population. Data pertaining to geriatric rehabilitation and geriatric dialysis rehabilitation were also reviewed. We show how disability and functional limitations are more prevalent in populations with advanced stages of chronic kidney disease (CKD) compared with those with only mild stages of CKD. We describe data showing that dedicated geriatric dialysis rehabilitation units, using interdisciplinary care models, result in more than 70% of patients meeting their rehabilitation goals and being successfully discharged home. Nephrologists increasingly will be faced with problems arising from functional decline. We conclude by offering suggestions for future changes that may help to stem the rising tide of dialysis disability.

Johansen KL, Delgado C, Bao Y, Kurella Tamura M. **Frailty and dialysis initiation.** *Semin Dial.* 2013 Nov-Dec;26(6):690-6. Epub 2013 Sep 4.

Notes: Qualitative review of concept of frailty in the CKD and ESRD populations, including information on impact of dialysis initiation and association with outcomes such as death or hospitalization.

Abstract: Frailty is a physiologic state of increased vulnerability to stressors that results from decreased physiologic reserves or dysregulation of multiple physiologic systems. The construct of frailty has been operationalized as a composite of poor physical function, exhaustion, low physical activity, and weight loss. Several studies have now examined the prevalence of frailty among chronic kidney disease (CKD) or end-stage renal disease (ESRD) patients and have found frailty to be more common among individuals with CKD than among those without. Furthermore, frailty is associated with adverse outcomes among incident dialysis patients, including higher risk of hospitalization and death. Recent evidence shows that frail patients are started on dialysis earlier (at a higher estimated glomerular filtration rate [eGFR]) on average than nonfrail patients, but it remains unclear whether these patients' frailty is a result of uremia or is independent of CKD. The survival disadvantage that has been associated with early initiation of dialysis in observational studies could be mediated in part through confounding on the basis of unmeasured frailty. However, available data do not

suggest improvement in frailty upon initiation of dialysis; rather, the trajectory appears to be toward higher levels of dependence in activities of daily living (ADLs) after dialysis initiation. Overall, there are no data to suggest that frail patients derive any benefit from early initiation of dialysis either in the form of improved survival or functional status.

Kalantar-Zadeh K, Unruh M. **Health related quality of life in patients with chronic kidney disease.** *Int Urol Nephrol.* 2005;37(2):367-78.

Notes: Qualitative review of concepts of HRQOL and functional status.

Abstract: Monitoring a patient's functional status and the subjective state of well being as it related to health condition, together known as health related quality of life (HRQOL) measurements, is of particular importance in patients with chronic kidney disease (CKD) including those with end stage renal disease (ESRD). The concept of quality of life in dialysis has evolved since the inception of renal replacement therapy from simple survival to enjoying a certain level of well being. The measurement of dialysis outcomes have paralleled the improvement in the delivery of renal replacement therapy progressing from level of functioning, symptom checklists, multi dimensional well being, and moving perhaps to more patient centered quality of life. HRQOL domains have been strongly associated with objective patient outcomes. The self reported physical functioning and mental well being correlate with serum albumin and body composition measures. The ability of those on hemodialysis to self administer questionnaires is a barrier to the widespread use of multidimensional HRQOL assessment in clinical practice. However, new technologies using computer adaptive testing and item response theory may allow those questionnaires to be quickly and more efficiently administered by clinic staff. The finding of different HRQOL scores among CKD patients of different racial and ethnic backgrounds supports the need to individualize the concept of HRQOL, so that we can assess the crucial aspects of life in our patients and integrate these domains into a comprehensive plan of care. These recent findings underline the critical need to measure HRQOL and to expand the boundaries of our multidimensional tools with technology and a more patient centered concept of quality of life.

Kim JC, Kalantar-Zadeh K, Kopple JD **Frailty and protein-energy wasting in elderly patients with end stage kidney disease.** *J Am Soc Nephrol.* 2013 Feb;24(3):337-51. Epub 2012 Dec 20.

Notes: Include as potential source for additional references as it is a recent review.

Abstract: Older people constitute an increasingly greater proportion of patients with advanced CKD, including those patients undergoing maintenance dialysis treatment. Frailty is a biologic syndrome of decreased reserve and resistance to stressors that results from cumulative declines across multiple physiologic systems and causes vulnerability to adverse outcomes. Frailty is common in elderly CKD patients, and it may be associated with protein-energy wasting (PEW), sarcopenia, dynapenia, and other complications of CKD. Causes of frailty with or without PEW in the elderly with CKD can be classified into three categories: causes primarily caused by aging per se, advanced

CKD per se, or a combination of both conditions. Frailty and PEW in elderly CKD patients are associated with impaired physical performance, disability, poorer quality of life, and reduced survival. Prevention and treatment of these conditions in the elderly CKD patients often require a multifaceted approach. Here, we examine the causes and consequences of these conditions and examine the interplay between frailty and PEW in elderly CKD patients.

Kosmadakis GC, Bevington A, Smith AC, et al. **Physical exercise in patients with severe kidney disease.** *Nephron Clin Pract.* 2010+ADs-115(1):c7-c16. Epub 2010 Feb 19.

Abstract: Patients with advanced chronic kidney disease (CKD), especially those on long-term dialysis, often suffer from muscle wasting and excessive fatigue. It is known that inactivity, muscle wasting and reduced physical functioning are associated with increased mortality in CKD. Known causes include uraemic myopathy and neuropathy, inactivity, and anaemia. Exercise in patients receiving regular dialysis treatment for end-stage renal disease was first introduced 3 decades ago, but is still only offered in a minority of renal units around the world, despite a significant body of evidence to support its use. Work is needed to increase awareness of the potential benefits of increased physical activity for patients with advanced CKD. This review summarizes the mechanisms of exercise intolerance and debility in advanced CKD patients, the methods used for the estimation of functional capacity, the options currently available for exercise training, and their influence on the well-being of this group of patients.

Kouidi, E **Health-related quality of life in end-stage renal disease patients: the effects of renal rehabilitation.** *Clin Nephrol.* 2004 May;61 Suppl 1:S60-71.

Notes: Qualitative review of the impact of physical rehabilitation in pts on dialysis.

Abstract: Health-related quality of life (HRQoL) consists of a number of components like functional status, psychological and social functioning, cognition and disease and treatment-related symptoms. End-stage renal disease (ESRD) patients display emotional disturbances, as well as non-adherence to treatment and fluid and food intake, depression, anxiety, social withdrawal and cardiovascular and other co-existing disease morbidity. They have very low functional capacity and physical limitations in their daily activities that affect their mortality and morbidity. Exercise training in ESRD patients is effective in increasing work related activities and important components of their daily life and improving physical functioning. A physical rehabilitation program also leads to a reduction in depression and improvement in family and social interactions. Therefore, renal rehabilitation should be considered as an important therapeutic method for improving physical fitness, social function, well-being and thus health-adjusted quality of life in ESRD patients.

Kutner NG **Assessing end-stage renal disease patients' functioning and well-being: measurement approaches and implications for clinical practice.** *Am J Kidney Dis.* 1994 Aug;24(2):321-33.

Notes: Qualitative review of issues relating to measuring functional status in dialysis patients.

Abstract: Along with survival and other types of clinical outcome, the functioning and well-being that characterize end-stage renal disease patients are important indicators of the effectiveness of the medical care that they receive. In addition, maximizing functioning in chronically ill patients can be viewed as secondary prevention. Patient-reported functioning and well-being indicate how patients are doing in their daily lives and how they feel about their lives. Measurements used to assess patient functioning and well-being by health services researchers are applicable to health outcome assessment in the clinical setting. Disease- and treatment-specific outcome measurements are more sensitive to disease severity and treatment intervention effects, while generic outcome measurements provide generalizability across diseases or conditions. Specific measurements can provide data about clinically meaningful changes, and generic measurements help to indicate the significance of these outcomes in patients' daily lives. Using both types of patient-reported measurements, as well as performance-based assessments, will provide outcome-based data on end-stage renal disease patients' functional limitation and disability, and help to define relevant rehabilitation protocols for end-stage renal disease patients.

Levin, N W **Quality of life and hematocrit level.** *Am J Kidney Dis.* 1992 Jul+ADs-20(1 Suppl 1):16-20.

Notes: Review of impact of correction of anemia with EPO in pts with ESRD.

Abstract: As the anemia that accompanies chronic renal failure (CRF) is successfully treated with recombinant human erythropoietin (epoetin), striking improvements in overall quality of life have been noted in several clinical studies of patients receiving chronic hemodialysis. A review of available clinical data has shown that, following epoetin therapy, peak oxygen consumption, a principal indicator of exercise ability, increased by approximately 50+ACU- as the hematocrit level increased. Following epoetin therapy in pediatric patients with end-stage renal disease (ESRD), the ventilatory anaerobic threshold (VAT) increased significantly and correlated well with increases in hemoglobin concentrations. Increased exercise capacity associated with the reversal of anemia appeared to positively effect many quality-of-life parameters. Analysis of questionnaires incorporating both subjective and objective quality-of-life indicators showed significant improvements between baseline and follow-up periods. Many patients experienced relief from some of the debilitating symptoms of anemia and many had significantly improved functional ability. Higher activity and energy levels were reflected in enhanced emotional and social well-being, with improvements noted in appetite, sleeping behavior, and sexual function. There was no change in the employment status of most patients. The extent of improvement in overall quality of life may be a function of the baseline level of impairment and the potential for reversal. However, baseline capabilities at rest may not be appropriate for physiologic studies.

Mercer TH, Koufaki P, Naish PF. **Nutritional status, functional capacity and exercise rehabilitation in end-stage renal disease.** *Clin Nephrol.* 2004 May+ADs-61 Suppl 1:S54-9.

Notes: Qualitative review of the impact of exercise in pts on dialysis.

Abstract: A significant percentage of patients with end-stage renal disease are malnourished and/or muscle wasted. Uremia is associated with decreased protein synthesis and increased protein degradation. Fortunately, nutritional status has been shown to be a modifiable risk factor in the dialysis population. It has long been proposed that exercise could positively alter the protein synthesis-degradation balance. Resistance training had been considered as the only form of exercise likely to induce anabolism in renal failure patients. However, a small, but growing, body of evidence indicates that for some dialysis patients, favourable improvements in muscle atrophy and fibre hypertrophy can be achieved via predominantly aerobic exercise training. Moreover, some studies tentatively suggest that nutritional status, as measured by SGA, can also be modestly improved by modes and patterns of exercise training that have been shown to also increase muscle fibre cross-sectional area and improve functional capacity. Functional capacity tests can augment the information content of basic nutritional status assessments of dialysis patients and as such are recommended for routine inclusion as a feature of all nutritional status assessments.

Painter P, Marcus RJL. **Assessing physical function and physical activity in patients with CKD.** *Clin J Am Soc Nephrol.* 2013 May; 8(5):861-72.

Abstract: Patients with CKD are characterized by low levels of physical functioning, which, along with low physical activity, predict poor outcomes in those treated with dialysis. The hallmark of clinical care in geriatric practice and geriatric research is the orientation to and assessment of physical function and functional limitations. Although there is increasing interest in physical function and physical activity in patients with CKD, the nephrology field has not focused on this aspect of care. This paper provides an in-depth review of the measurement of physical function and physical activity. It focuses on physiologic impairments and physical performance limitations (impaired mobility and functional limitations). The review is based on established frameworks of physical impairment and functional limitations that have guided research in physical function in the aging population. Definitions and measures for physiologic impairments, physical performance limitations, self-reported function, and physical activity are presented. On the basis of the information presented, recommendations for incorporating routine assessment of physical function and encouragement for physical activity in clinical care are provided.

Parsons TL, King-Vanvlack CE. **Exercise and end-stage kidney disease: functional exercise capacity and cardiovascular outcomes.** *Adv Chronic Kidney Dis.* 2009 Nov+ADs-16(6):459-81.

Notes: Review of impact of exercise in ESRD pts.

Abstract: This review examined published reports of the impact of extradialytic and intradialytic exercise programs on physiologic aerobic exercise capacity, functional exercise endurance, and cardiovascular outcomes in individuals with ESKD. Studies spanning 30 years from the first published report of exercise in the ESKD population were reviewed. Studies conducted in the first half of the publication record focused on the efficacy of exercise training programs performed +ACI-off+ACI--

dialysis with respect to the modification of traditional cardiovascular risk factors, aerobic capacity, and its underlying determinants. In the latter half of the record, there had been a shift to include other client-centered goals such as physical function and quality of life. There is evidence that both intra- and extradialytic programs can significantly enhance aerobic exercise capacity, but moderate-intensity extradialytic programs may result in greater gains in those individuals who initially have extremely poor aerobic capacity. Functionally, substantive improvements in exercise endurance in excess of the minimum clinical significant difference can occur following either low- or moderate-intensity exercise regardless of the initial level of performance. Reductions in blood pressure and enhanced vascular functioning reported after predominantly intradialytic exercise programs suggest that either low- or moderate-intensity exercise programs can confer cardiovascular benefit. Regardless of prescription model, there was an overall lack of evidence regarding the impact of exercise-induced changes in exercise capacity, endurance, and cardiovascular function on a number of relevant health outcomes (survival, morbidity, and cardiovascular risk), and, more importantly, there is no evidence on the long-term impact of exercise and/or physical activity interventions on these health outcomes.

Sabath, R J **Exercise evaluation of children with end-stage renal disease.** *Adv Ren Replace Ther.* 1999 Apr+ADs-6(2):189-94.

Notes: Review of exercise testing in pediatric ESRD pts.

Abstract: The use of exercise testing in the assessment and management of various pediatric disorders has increased significantly during the past three decades. With age-appropriate equipment and exercise protocols, a well-trained and enthusiastic staff can evaluate patients as young as 3 to 4 years of age. Pediatric exercise testing may be conducted using either a cycle ergometer or a treadmill. The decision of which method to use is based on the parameters to be evaluated during the test, physical stature of the child, administrator preference, and availability of equipment in the laboratory. For children with renal disease, who are often short and may have poor leg muscle mass, the treadmill is used most often. The exercise testing protocols should use slow initial speeds and no grade, increase in small increments, and have stages of 1 to 2 minutes' duration. The benefits of testing in children with renal disorders include its ability to provide valuable information regarding the overall functional capacity of the patient, efficacy of pharmacological or surgical interventions, and outcome of rehabilitation programs.

van Nooten FE, Green J, Brown R, Finkelstein FO, Wish J. **Burden of illness for patients with non-dialysis chronic kidney disease and anemia in the United States: review of the literature.** *J Med Econ.* 2010;13(2):241-56.

Notes: Systematic review of impact of anemia and its correction on a host of outcomes, including HRQOL, functional status. Focused on non-dialysis CKD population, though implications likely relevant for dialysis population as well.

Abstract: OBJECTIVE: To assess the health-related quality of life (HRQL) and economic burden of chronic kidney disease (CKD) related anemia in non-dialysis patients in the United States (US) via literature review. METHODS: MEDLINE, EMBASE, PROQOLID, and Cochrane Library/Renal Group Resources were searched. Studies were appraised for patient populations, disease-specific versus generic HRQL assessments, and type and magnitude of health-related costs. RESULTS: The treatment costs for CKD patients with anemia compared to those without anemia were significantly higher and were blunted but persistent after controlling for comorbidities and confounders. Intervention with erythropoiesis stimulating agents (ESA) decreased anemia and avoided hospital admissions. Costs were higher when anemia was poorly controlled or untreated. HRQL burden was mainly due to physical limitations and difficulty in ability to perform activities of daily living. Significant positive correlations between increases in hemoglobin levels and HRQL measures were reported. CONCLUSIONS: Although evidence is limited, the economic and HRQL burden of non-dialysis CKD-related anemia is substantial. Under-treatment of anemia may contribute to higher resource consumption and higher costs; however, patient co-morbidities, use of erythropoietin-stimulating agents, and overall management introduce potential confounds. The contribution of anemia to humanistic disease burden is due to a constellation of factors, including physical activity and functional status.

Walker SR, Gill K, Macdonald K, Komenda P, et al. **Association of frailty and physical function in patients with non-dialysis CKD: a systematic review.** *BMC Nephrol.* 2013 Oct 22;14(1):228.

Notes: Systematic review of frailty and CKD and associated outcomes.

Abstract: BACKGROUND: Frailty is a condition characterized by a decline in physical function and functional capacity. Common symptoms of frailty, such as weakness and exhaustion, are prevalent in patients with chronic kidney disease (CKD). The increased vulnerability of frail patients with coexisting CKD may place them at a heightened risk of encountering additional health complications. The purpose of this systematic review was to explore the link between frailty, CKD and clinical outcomes. METHODS: We searched for cross sectional and prospective studies in the general population and in the CKD population indexed in EMBASE, Pubmed, Web of Science, CINAHL, Cochrane and Ageline examining the association between frailty and CKD and those relating frailty in patients with CKD to clinical outcomes. RESULTS: We screened 5,066 abstracts and retrieved 108 studies for full text review. We identified 7 studies associating frailty or physical function to CKD. From the 7 studies, we identified only two studies that related frailty in patients with CKD to a clinical outcome. CKD was consistently associated with increasing frailty or reduced physical function [odds ratios (OR) 1.30 to 3.12]. In patients with CKD, frailty was associated with a greater than two-fold higher risk of dialysis and/or death [OR from 2.0 to 5.88]. CONCLUSIONS: CKD is associated with a higher risk of frailty or diminished physical function. Furthermore, the presence of frailty in patients with CKD may lead to a higher risk of mortality. Further research must be conducted to understand the mechanisms of frailty in CKD and to confirm its association with clinical outcomes.

Non-ESRD

Association with Outcomes

Broadwin J, Goodman-Gruen D, Slymen D. **Ability of fat and fat-free mass percentages to predict functional disability in older men and women.** *J Am Geriatr Soc.* 2001 Dec;49(12):1641-5.

Notes: Cross-sectional and prospective study (n=1051) of ambulatory adults correlating measurement of percentage fat mass and measures of functional ability.

Abstract: OBJECTIVES: Previous studies suggest an association between body composition and declining functional ability in older people. This study examined the relation between functional disability and percentage of fat mass (FM) and percentage of fat-free mass (FFM) in older men and women. DESIGN: Cross-sectional and prospective. SETTING: Rancho Bernardo, California. PARTICIPANTS: Subjects consisted of 1,051 ambulatory, community-dwelling Caucasian men and women, age 55 to 92, who attended a clinic visit between 1988 and 1992 and a subsequent clinic visit between 1992 and 1996. MEASUREMENTS: Measured at both visits, percentage of fat mass and percentage of lean body mass were estimated by bioelectric impedance analysis and functional disability was ascertained by self-administered questionnaire. Functional disability was dichotomized into those having any difficulty with a set of tasks versus those having no difficulty with the tasks. Two measures of functional disability were used: "lower body" disability, consisting of two lower motor tasks (walking 2-3 blocks and climbing up 10 stairs) and "overall" disability, consisting of nine tasks representing upper and lower body function and mobility. RESULTS: Compared with men, women were more likely to report both lower body and overall functional disability (P=.001). Cross-sectionally, a significant positive association was shown between fat mass and overall functional disability and a significant negative association was shown between FFM and overall functional disability in both men and women. Prospectively, increased percentage of body fat and decreased percentage of FFM were significantly associated with decreased functional ability in both women and men. All results were adjusted for age, smoking, alcohol use, physical activity, current estrogen use, depression, chronic disease, and education. CONCLUSION: Increased percentage of fat mass and decreased percentage of FFM are associated with greater functional disability in older men and women. Further research is needed to assess the relative importance of decreasing fat percentage or increasing fat-free percentage to preserve or improve functional ability in older people.

Di Fazio I, Franzoni S, Frisoni GB, et al. **Predictive role of single diseases and their combination on recovery of balance and gait in disabled elderly patients.** *J Am Med Dir Assoc.* 2006 May;7(4):208-11. Epub 2006 Mar 3.

Notes: Observational, single center study (n=710) describing the differences in likelihood of successful discharge from inpatient rehab as a function of principal disease/organ system. It is of

some interest that kidney disease was not considered a "more disabling disease" and was not associated with lower likelihood of successful discharge from inpatient rehab. This study may not be very useful to the TEP if the kidney disease category is heterogeneous. However, if the investigators definition of kidney disease relates to advanced CKD and/or ESRD, then there may be some information of use here.

Abstract: OBJECTIVES: In the elderly population, chronic diseases are common determinants of mobility limitations and comorbidity consistently shows a strong association with functional status. This study was designed to evaluate the role of single chronic diseases and of their combination on functional recovery after rehabilitative treatment in disabled elderly patients. DESIGN: With respect to the difference in magnitude of their disabling effect, diseases were classified into 2 groups: "more disabling" diseases (COPD, heart failure, peripheral artery diseases, diabetes, and not life-threatening cancer) and "less disabling" diseases (anemia, kidney, gastrointestinal, and liver diseases). SETTING: 35-bed Geriatric Evaluation and Rehabilitation Unit. PARTICIPANTS: We studied 710 patients (age 77.8 7.4 years, 76.2% females), consecutively admitted for stroke, Parkinson's disease, and osteoarthritis. MEASUREMENTS: A multidimensional evaluation for mobility (Tinetti-score), cognitive status (MMSE), and somatic health (Greenfield's Individual Disease Severity Index-IDS, Burden of diseases-BoD) was performed. Functional recovery was decided based on the Delta-Tinetti, which is the difference of the values between admission and discharge. RESULTS: We tested, in a multivariate regression model, the predictive role of single chronic conditions and of their combinations on functional recovery, after having adjusted for which diseases are direct causes of disability (stroke, Parkinson's disease, and osteoarthritis) and other potential predictors (age, sex, cognitive function, depressive symptoms, albumin, and c-reactive protein). A negative prediction of functional recovery was expressed by the "more disabling" diseases group. The determinants of poor recovery were characterized by the combination of "more disabling diseases" rather than single condition effects, independently by age, cognitive, and functional status on admission. CONCLUSION: Our study adds a new perspective about the role of COPD, heart failure, peripheral artery diseases, diabetes and not life-threatening cancer on functional recovery, emphasizing their combined impact in elderly people.

*Ferrucci L, Penninx BW, Leveille SG, Corti MC, Pahor M, Wallace R, Harris TB, Havlik RJ, Guralnik JM.

Characteristics of nondisabled older persons who perform poorly in objective tests of lower extremity function. *J Am Geriatr Soc.* 2000 Sep;48(9):1102-10.

Abstract: OBJECTIVES: It has been suggested that nondisabled older persons with poor performance of lower extremity function are ideal targets for interventions of disability prevention. However, health-related factors associated with poor performance are largely unknown. Using data from a representative sample of nondisabled older persons, this study identifies the diseases and biological markers that characterize this group of the population. DESIGN AND PARTICIPANTS: A total of 3,381 persons aged 71 or older, interviewed and administered a battery of physical performance tests at the sixth annual follow-up of the Established Populations for Epidemiologic Studies of the Elderly

(EPESE), who reported no need for help in walking 1/4 mile or climbing stairs. **MEASUREMENTS:** Lower extremity performance was measured using a short battery of tests including assessment of standing balance, a timed 2.4-m walk, and timed test of rising 5 times from a chair. Chronic conditions were ascertained as self-report of a physician diagnosis. Data on previous hospitalizations were obtained from the Medicare database. Nonfasting blood samples were obtained and processed with standard methods. **RESULTS:** In a multivariate analysis, older age, female gender, higher BMI, history of hip fracture and diabetes, one or more hospital admissions for acute infection in the last 3 years, lower levels of hemoglobin and albumin, and higher leukocytes and gamma-glutamyl transferase were all associated independently with poor performance. **CONCLUSIONS:** Screening for older patients who are not disabled but have poor lower extremity performance selects a subgroup of the population with a high percentage of women, high prevalence of diabetes and hip fracture, and high levels of biological markers of inflammation. This group represents about 10% of the US population 70 to 90 years old. These findings should be considered in planning specifically tailored interventions for disability prevention in this subgroup.

Fried TR, Bradley EH, Williams CS, Tinetti ME. **Functional disability and health care expenditures for older persons.** *Arch Intern Med.* 2001 Nov 26;161(21):2602-7.

Notes: Cohort study describing costs and service utilization associated with functional dependence.

Abstract: **BACKGROUND:** The rapidly expanding proportion of the US population 65 years and older is anticipated to have a profound effect on health care expenditures. Whether the changing health status of older Americans will modulate this effect is not well understood. This study sought to determine the relationship between functional status and government-reimbursed health care services in older persons. **METHODS:** Longitudinal cohort study of a representative sample of community-dwelling persons 72 years or older. Clinical data were linked with data on 2-year expenditures for Medicare-reimbursed hospital, outpatient, and home care services and Medicare- and Medicaid-reimbursed nursing home services. Per capita expenditures associated with different functional status transitions were calculated, as were excess expenditures associated with functional disability adjusted for demographic, health, and psychosocial variables. **RESULTS:** The 19.6% of older persons who had stable functional dependence or who declined to dependence accounted for almost half (46.3%) of total expenditures. Persons in these groups had an excess of approximately \$10 000 in expenditures in 2 years compared with those who remained independent. The 9.6% of patients who were dependent at baseline accounted for more than 40.0% of home health and nursing home expenditures; the 10.0% who declined accounted for more than 20.0% of hospital, outpatient, and nursing home expenditures. **CONCLUSIONS:** Functional dependence places a large burden on government-funded health care services. Whereas functional decline places this burden on short- and long-term care services, stable functional dependence places the burden predominantly on long-term care services. Declining rates of functional disability and interventions to prevent disability hold promise for ameliorating this burden.

Givens JL, Sanft TB, Marcantonio ER. **Functional recovery after hip fracture: the combined effects of depressive symptoms, cognitive impairment, and delirium.** *J Am Geriatr Soc.* 2008 Jun;56(6):1075-9. Epub 2008 Apr 18.

Notes: Included as evidence of the association between cognitive function and result of rehabilitation (not in ESRD). May need literature justification of use of the cognitive assessment CARE tool in dialysis facilities as a meaningful component of rehabilitation potential and result.

Abstract: OBJECTIVES: To measure the prevalence of depressive symptoms, cognitive impairment, and delirium in patients with hip fracture and to estimate their effect on functional recovery, institutionalization, and death after surgical repair. DESIGN: Prospective cohort. SETTING: Hospital, follow-up to community and nursing home. PARTICIPANTS: One hundred twenty-six patients aged 65 and older admitted for hip fracture repair. MEASUREMENTS: Baseline measurements: Mini-Mental State Examination, Blessed Dementia Rating Scale, Geriatric Depression Scale, prefracture activities of daily living (ADLs), ambulatory status. The Confusion Assessment Method was used to diagnose in-hospital delirium. One- and 6-month outcomes were ADL decline, loss of ambulation, and new nursing home placement or death. RESULTS: Twenty-two percent of patients had one cognitive or mood disorder, 30% had two, and 7% had three. At 1 month, each cognitive or mood disorder was independently associated with one or more adverse outcome. Considered together, each additional cognitive or mood disorder was associated with greater odds of 1 month outcomes (ADL decline: odds ratio (OR)=1.8, 95% confidence interval (CI)=1.1-2.9; decline in ambulation: OR=1.8, 95% CI=1.1-3.0; nursing home placement or death: OR=3.9, 95% CI=1.9-8.1). CONCLUSION: Cognitive and mood disorders were common in elderly hip fracture patients and were associated with greater risk of poor outcomes, both independently and in combination. Recognition and treatment of these conditions may reduce adverse outcomes in this vulnerable population.

Montero-Odasso M, Schapira M, Soriano ER, et al. **Gait velocity as a single predictor of adverse events in healthy seniors aged 75 years and older.** *J Gerontol A Biol Sci Med Sci.* 2005 Oct;60(10):1304-9.

Notes: Cohort study of ambulatory adults aged 75 years or older showing an association between gait velocity and adverse outcomes such as hospitalization.

Abstract: PURPOSE: Although gait velocity (GV) measurement could predict poor outcomes, few studies regarding its usefulness as a single test in well functioning elderly persons have been pursued. The aim of this study was to assess whether GV could be sufficient to predict adverse events such as hospitalization for any cause, requirement for a caregiver, nursing home placement, falls, fractures, or death in healthy elderly persons. METHODS: Ours was a cohort study comprising 102 well functioning participants aged 75 and older. Demographic features, health status, and functional capacity were assessed at baseline and followed for adverse outcomes. Measurements included evaluation of cognition, activities of daily living, and mobility. The time required to walk the

middle 8 meters of 10 meters was defined as GV. Three GV groups were distinguished: high GV (>1.1 m/s), median GV (1-0.7 m/s), and low GV (<0.7 m/s). RESULTS: At baseline, the three groups were comparable in their health status with an average age of 79.6 +/- 4 years. At 24 months, the low GV group had a significantly higher incidence of adverse events than did the other groups. Low GV was a predictor of hospitalization (relative risk [RR] = 5.9, 95% confidence interval [CI], 1.9-8.5), requirement of a caregiver (RR = 9.5, 95% CI, 1.3-2.5), and new falls (RR = 5.4, 95% CI, 2.0-4.3). These associations remained significant after a multiple logistic regression analysis. CONCLUSIONS: GV measurement in the ambulatory setting may allow the detection of healthy elderly people at risk for adverse events. These data may suggest that simple assessment of GV is enough to predict adverse events in well functioning older persons.

Nelson E, Conger B, Douglass R, et al. **Functional health status levels of primary care patients.** *JAMA.* 1983 Jun 24;249(24):3331-8.

Abstract: A cross-sectional study was conducted on functional status of adults visiting primary care practices. Limitations in physical and mental function were assessed independently in 28 practices by patients (N = 1,227) and physicians (N = 47) using a simple global index of disability. Results indicated 12% of patients rated their physical limitations as major and 8% rated major emotional limitations during the past month. Comparable assessments by physicians were 5% and 4%, respectively. Differences between patients and physicians were statistically significant and are demonstrated to be clinically relevant. Patients' functional limitations were associated with increased utilization of ambulatory care, older age, lower level of education, unemployment, and a primary diagnosis of a chronic condition. We conclude that functional status can be routinely recorded in medical practice to help describe severity, predict utilization, and improve the physician-patient relationship.

Oh-Park M, Wang C, Verghese J. **Stair negotiation time in community-dwelling older adults: normative values and association with functional decline.** *Arch Phys Med Rehabil.* 2011 Dec;92(12):2006-11.

Notes: Longitudinal cohort study (n=513) in ambulatory older adults validating stair ascent/descent times as predictors of functional decline.

Abstract: OBJECTIVES: To establish reference values for stair ascent and descent times in community-dwelling, ambulatory older adults, and to examine their predictive validity for functional decline. DESIGN: Longitudinal cohort study. Mean follow-up time was 1.8 years (maximum, 3.2y; total, 857.9 person-years). SETTING: Community sample. PARTICIPANTS: Adults 70 years and older (N=513; mean age, 80.8 +/- 5.1y) without disability or dementia. INTERVENTIONS: Not applicable. MAIN OUTCOME MEASURES: Time to ascend and descend 3 steps measured at baseline. A 14-point disability scale assessed functional status at baseline and at follow-up interviews every 2 to 3 months. Functional decline was defined as an increase in the disability score by 1 point during the follow-up period. RESULTS: The mean +/- SD stair ascent and descent times for 3 steps were 2.78 +/-

1.49 and 2.83 +/- 1.61 seconds, respectively. The proportion of self-reported and objective difficulty was higher with longer stair ascent and descent times ($P < .001$ for trend for both stair ascent and descent). Of the 472 participants with at least 1 follow-up interview, 315 developed functional decline, with a 12-month cumulative incidence of 56.6% (95% confidence interval [CI], 52.1%-61.3%). The stair negotiation time was a significant predictor of functional decline after adjusting for covariates including gait velocity (adjusted hazard ratio [aHR] per 1-s increase: aHR=1.12 [95% CI, 1.04-1.21] for stair ascent time; aHR=1.15 [95% CI, 1.07-1.24] for stair descent time). Stair descent time was a significant predictor of functional decline among relatively high functioning older adults reporting no difficulty in stair negotiation ($P = .001$). **CONCLUSIONS:** The stair ascent and descent times are simple, quick, and valid clinical measures for assessing the risk of functional decline in community-dwelling older adults including high-functioning individuals.

Reuben DB, Siu AL, Kimpau S. **The predictive validity of self-report and performance-based measures of function and health.** *J Gerontol.* 1992 Jul;47(4):M106-10.

Notes: Longitudinal cohort study (n=149) of older adults showing association between various functional status instruments and mortality.

Abstract: To learn about the value of self-report and performance-based measures of function in predicting mortality and institutionalization, we conducted a longitudinal study of 149 elderly persons at four sites (a senior citizens housing unit, two ambulatory-based geriatrics practices, and a board-and-care facility). At baseline, all subjects were administered a questionnaire containing Katz, Spector, and Rosow-Breslau scale items as well as the Mini-Mental State Exam and two performance-based measures, the Tinetti gait score and Physical Performance Test. At follow-up (average 22 months; range 17-29 months), 17 subjects (11%) had died and seven (5%) had been institutionalized. Univariate analysis demonstrated significant associations between death and all functional status measures. In logistic regression models, Katz items, Tinetti gait score, and the seven-item Physical Performance Test were independent predictors of "death or nursing home placement"; Katz items and the seven-item Physical Performance Test were independent predictors of mortality. These findings support the use of performance-based as well as self-report measures for clinical and research purposes.

Ruchinkas RA, Singer HK, Repetz NK. **Cognitive status and ambulation in geriatric rehabilitation: walking without thinking?** *Arch Phys Med Rehabil.* 2000 Sep;81(9):1224-8.

Notes: Included as evidence of the association between cognitive function and result of rehabilitation (not in ESRD). May need literature justification of use of the cognitive assessment CARE tool in dialysis facilities as a meaningful component of rehabilitation potential and result.

Abstract: **OBJECTIVE:** To assess the relation between cognitive and ambulatory abilities in geriatric rehabilitation inpatients. **STUDY DESIGN:** Survey study of geriatric cohorts. **SETTING:** Inpatient

university hospital rehabilitation unit. PATIENTS: One hundred fifty urban geriatric rehabilitation patients with orthopedic, neurologic, or medical diagnoses. MAIN OUTCOME MEASURES: Functional Independence Measure (FIM), Mattis Dementia Rating Scale, Neurobehavioral Cognitive Status Examination. RESULTS: Both cognitive measures predicted admission and discharge total FIM scores, continence status, and activities of daily living (ADL) scores. Neither measure could predict admission or discharge FIM ambulation scores better than demographic variables. CONCLUSION: While cognitive status affects the overall rehabilitation course and ultimate functional status of the geriatric patient, it does not predict walking or stair climbing ability.

*Stewart TV, Loskutova N, Galliher JM, et al. **Practice Patterns, Beliefs, and Perceived Barriers to Care Regarding Dementia: A Report from the American Academy of Family Physicians (AAFP) National Research Network.** *J Am Board Fam Med* 2014;27:275–283.

Abstract: PURPOSE: Given the increasing age of the US population, understanding how primary care is delivered surrounding dementia and physicians' perceived barriers and needs associated with this care is essential. METHODS: A 29-item questionnaire was developed by project investigators and family physician consultants and mailed to a random sample of 1500 US members of the American Academy of Family Physicians in 2008; 2 follow-up mailings were sent to nonrespondents. Physicians were queried about sociodemographic characteristics, practice patterns, and beliefs (including challenges, barriers, and needs) about care processes focusing on dementia among older patients. RESULTS: The response rate was 60%, with respondents statistically comparable ($P > .05$) to the American Academy of Family Physicians physician population. Among physicians, 93% screen and/or conduct diagnostic evaluations for dementia in older patients, whereas 91% provide ongoing primary care for patients with dementia whether or not they screen for or diagnose dementia. Forty percent of physicians refer some patients with suspected dementia to other providers (primarily neurologists) to verify diagnosis, for comanagement, or both. Factors affecting the diagnosis of dementia and the delivery of dementia care included patient behavior challenges (aggressiveness, restlessness, paranoia, wandering); comorbidities (falls, delirium, adverse medication reactions, urinary incontinence); caregiver challenges (fatigue, planning for patient's institutional placement, anger); and structural barriers (clinician time, time required for screening, limited treatment options). Tools needed to provide enhanced dementia care included better assessment tools, community resources, and diagnostic and screening tools. CONCLUSION: Family physicians are highly involved in the assessment and routine care of patients with suspected dementia or diagnosed with dementia, although a relative few are not. This is despite the recognized challenges physicians encounter in the assessment and care processes.

Trappenburg JC, Troosters T, Spruit MA, et al. **Psychosocial conditions do not affect short-term outcome of multidisciplinary rehabilitation in chronic obstructive pulmonary disease.** *Arch Phys Med Rehabil.* 2005 Sep;86(9):1788-92.

Notes: Included as evidence of the association between cognitive function and result of rehabilitation (not in ESRD). May need literature justification of use of the cognitive assessment CARE tool in dialysis facilities as a meaningful component of rehabilitation potential and result.

Abstract: OBJECTIVES: To characterize patients referred for pulmonary rehabilitation on a large number of psychologic and sociodemographic variables and to determine the contribution of these variables on the response to rehabilitation. DESIGN: Cross-sectional, explorative. SETTING: University hospital and outpatient clinic. PARTICIPANTS: Eighty-one consecutive patients with chronic obstructive pulmonary disease (forced expiratory volume in 1 second, 40%+/-16% of predicted) were included in outpatient pulmonary rehabilitation. INTERVENTION: Multidisciplinary rehabilitation program. MAIN OUTCOME MEASURES: Pulmonary function, exercise capacity (Wmax, 6-minute walk test [6MWT]), Chronic Respiratory Disease Questionnaire (CRDQ), Modified Pulmonary Functional Status and Dyspnea Questionnaire (PFSDQ-M), anxiety and depression (Hospital Anxiety and Depression Scale [HADS]) were assessed before and after 3 months rehabilitation. In addition, psychosocial adjustment, social support, marital status, mode of transportation, education, employment, and smoking status were assessed at the start of the rehabilitation. RESULTS: Rehabilitation improved exercise performance (Wmax, 6+/-12W; P<.01; 6MWT, 41+/-72 m; P<.001), quality of life (CRDQ score, 12+/-13 points; P<.001), functional status (PFSDQ-M activity score, -8+/-11 points; PFSDQ-M dyspnea score, -6+/-12 points; PFSDQ-M fatigue score, -4+/-8 points; all P<.01), HADS anxiety score (-2+/-3 points, P<.01), and HADS depression score (-3+/-3 points, P<.001). In single regression analysis, only baseline depression was weakly negatively correlated with the change in maximal workload. No other relations of initial psychologic or sociodemographic variables with outcome were observed. CONCLUSIONS: The effects of rehabilitation are not affected by baseline psychosocial factors. Patients with less favorable psychologic or sociodemographic conditions can also benefit from pulmonary rehabilitation. The multidisciplinary approach of the rehabilitation program might have contributed to this improvement.

Vogt L, Wieland K, Bach M, Himmelreich H, Banzer W. **Cognitive status and ambulatory rehabilitation outcome in geriatric patients.** *J Rehabil Med.* 2008 Nov;40(10):876-8.

Notes: Included as evidence of the association between cognitive function and result of rehabilitation (not in ESRD). May need literature justification of use of the cognitive assessment CARE tool in dialysis facilities as a meaningful component of rehabilitation potential and result.

Abstract: OBJECTIVE: To determine the effect of admission cognitive status on gait and stair climbing rehabilitation outcome in geriatric patients. DESIGN: Before-after trial. SUBJECTS: A total of 179 geriatric patients (139 women and 40 men; age range 67-97 years) consecutively admitted to a geriatric inpatient rehabilitation regimen (mean length of stay 28.7 (standard deviation 13.9) days). METHODS: Assessment of admission cognitive status by the Mini-Mental State Examination (MMSE); determination of the ambulatory status before and after rehabilitation by the Performance-

Oriented Mobility Assessment (POMA) and standardized judgements about stair climbing ability. RESULTS: Approximately two-thirds of the patients demonstrated functional ability improvements in at least 5 points at the individual level during rehabilitation (as measured by the total POMA scale (POMA-T)). However, at rehabilitation discharge cognitively impaired patients still demonstrated a 3.4 times (95% confidence interval=1.4-8.6) higher chance of increased fall risk and only 24% of the cohort was able to negotiate stairs with slight or no limitations. CONCLUSION: Although cognitively impaired patients demonstrated an functional overall intervention response comparable with cognitively intact patients the present study evidenced that the geriatric cohort with reduced mental status (MMSE >17) are at greater risk of falling and have a greater need for supervision, both in hospital and at discharge.

Yu F, Evans LK, Sullivan-Marx EM. **Functional outcomes for older adults with cognitive impairment in a comprehensive outpatient rehabilitation facility.** *J Am Geriatr Soc.* 2005 Sep;53(9):1599-606.

Notes: Included as evidence of the association between cognitive function and result of rehabilitation (not in ESRD). May need literature justification of use of the cognitive assessment CARE tool in dialysis facilities as a meaningful component of rehabilitation potential and result.

Abstract: The purpose of the study was to examine functional outcomes of a nurse-managed, community-based Comprehensive Outpatient Rehabilitation Facility (CORF) for frail older adults and to compare the outcomes between two groups: older adults with cognitive impairment and those with intact cognition. A retrospective cohort design using healthcare record abstraction was used for the study. Two hundred and one older adults who were admitted to the CORF from the end of 1997 to early 1999 were included in the study. Data were abstracted from healthcare records, including clinician-generated Mini-Mental State Examination, Geriatric Depression Scale, and Functional Independence Measure scores from the healthcare records and investigator-constructed measures of functional gain, rehabilitation efficiency, days of service, and discharge location. Multivariate regression analyses were performed to compare rehabilitation outcomes between the two groups. Regardless of cognitive status, all subjects improved significantly in their levels of functional dependence through participating in this outpatient rehabilitation program ($P < .001$). Subjects with cognitive impairment exhibited more functional dependence at baseline and discharge than did their cognitively intact counterparts. Nevertheless, there was no difference between the two groups in functional gain ($P = .63$), rehabilitation efficiency ($P = .66$), days of service ($P = .83$), or discharge location ($P = .69$). Therefore, despite their greater degree of functional dependence on admission, older adults with cognitive impairment benefited from this CORF without requiring more days of service and should thus be referred for rehabilitation services.

Development and Validation of Instruments

Alessi CA, Josephson KR, Harker JO, et al. **The yield, reliability, and validity of a postal survey for screening community-dwelling older people.** *J Am Geriatr Soc.* 2003 Feb;51(2):194-202.

Notes: Large longitudinal cohort study (n=2382) in the VA validating an instrument, the Geriatric Postal Screening Survey (GPSS) for identifying aspects of functional status, and predicting risk for adverse outcomes such as hospitalization.

Abstract: OBJECTIVES: To assess the yield, reliability, and validity of a postal survey developed to identify older persons in need of outpatient geriatric assessment and follow-up services. DESIGN: A longitudinal cohort study. SETTING: Outpatient primary care clinic at a Department of Veterans Affairs teaching ambulatory care center. PARTICIPANTS: Patients (N = 2,382) aged 65 and older who returned a Geriatric Postal Screening Survey (GPSS) that screened for common geriatric conditions (depression, cognitive impairment, urinary incontinence, falls, and functional status impairment). Validity and reliability testing was performed with subsamples of patients classified as high or lower risk based on responses to the GPSS. MEASUREMENTS: Test-retest reliability was measured by percentage agreement and kappa statistic. The diagnostic validity of the 10-item GPSS was tested by comparing single GPSS items to standardized geriatric assessment instruments for depression, mental status and functional status, as well as direct questions regarding falls, urinary incontinence, and use of medications. Validity was also tested against clinician evaluation of the specific geriatric conditions. Predictive validity was tested by comparing GPSS score with 1-year follow-up data on functional status, survival, and healthcare use. RESULTS: Respondents identified as high risk by the GPSS had scores that indicated significantly greater impairment on structured assessment instruments than those identified as lower risk by GPSS. The overall mean percentage agreement between the test and retest surveys was 88.3%, with a mean weighted kappa of 0.70. In comparison with a structured telephone interview and with a clinical assessment, individual items of the GPSS showed good accuracy (range 0.71-0.78) for identifying symptoms of depression, falls, and urinary incontinence. Over a 1-year follow-up period, the GPSS-identified high-risk group had significantly ($P < .05$) more hospital admissions, hospital days and nursing home admissions than the lower-risk group. CONCLUSION: A brief postal screening survey can successfully target patients for geriatric assessment services. In screening for symptoms of common geriatric conditions, the GPSS identified a subgroup of older outpatients with multiple geriatric syndromes who were at increased risk for hospital use and nursing home admission and who could potentially benefit from geriatric intervention.

*Berková M, Topinková E, Mádlová P, et al. **The "Short Physical Performance Battery" in the Czech Republic - the pilot and validation study in older persons.** *Vnitr Lek.* 2013 Apr;59(4):256-63. Czech

Abstract: INTRODUCTION: Population ageing increases number of seniors with decline of physical capabilities and functional deficits. Targeted interventions to maintain or increase physical performance are most effective before the development of full frailty, in so-called "prefrail" period. One of the assessment tools for evaluation of the physical performance and/or frailty in older persons is the "Short Physical Performance Battery" - SPPB. The aim of the study was to introduce the assessment battery to clinical practice in the CR and to evaluate its selected psychometric properties. METHOD: Original English SPPB was translated into Czech language and back translated

to ensure linguistic accuracy. SPPB was applied in the selected sample of older persons and validated against other performance tools for cognition, self-care and nutrition status used in CR and selected psychometric properties evaluated. RESULTS: We examined 145 older persons (108 women, i.e. 74.48 % and 37 men, i.e. 25.52 %) mean age 80.38 years (54- 101 years, SD \pm 8,47). We found good physical performance in 35 (24.1 %) older persons (SPPB 10- 12 points), 21 (14.5 %) were identified as prefrail (SPPB 7-9 points) and 89 (61.4 %) as frail in high risk of future disability or already disabled (SPPB 6 points). We found statistically significant correlation of global SPPB score with nutritional status (MNA- Short Form), activities of daily living performance (ADL) and cognitive performance (MMSE) - (Spearman correlation ρ = 0.51; 0.53 and 0.38 respectively). The Cronbachs α for SPPB variables scored 0.821, which is consistent with good internal consistency of SPPB battery. When evaluating 3 age groups [75 years (n = 41), 76-85 (n = 62) and 86- 101 years (n = 42)] the most significant correlations were found between SPPB and MNA, ADL and MMSE in the young elderly (ρ = 0.74, 0.79 and 0.64 respectively) and they diminished with increasing age. CONCLUSION: We confirmed significant correlations between SPPB and self care activities, cognitive performance and nutritional status and good internal consistency of the battery. SPPB test is simple, easy to perform, with low time and cost requirements. It could be recommended for clinical practice in both community and hospitalized older patients to evaluate their overall physical performance and identify persons at risk of frailty and disability who may profit from targeted interventions.

Brooks D, Davis AM, Naglie G. **Validity of 3 physical performance measures in inpatient geriatric rehabilitation.** *Arch Phys Med Rehabil.* 2006 Jan;*87(1):105-10.*

Notes: Three center study in inpatient geriatric rehabilitation setting (n=52), validating the Timed Up & Go (TUG) and two-minute walk instruments for assessment of functional status as assessed by the FIM instrument and the Modified Barthel Index.

Abstract: OBJECTIVE: To evaluate the construct validity and the responsiveness of 3 measures of physical performance measures as outcome measures for frail older persons. DESIGN: Pre-post design with measures at admission and discharge. SETTING: Three inpatient geriatric rehabilitation programs. PARTICIPANTS: Fifty-two subjects (35 women, 17 men; age, 80+/-8y). INTERVENTIONS: Not applicable. MAIN OUTCOME MEASURES: Physical performance measures were Timed Up & Go (TUG) test, two-minute walk test (2MWT), and functional reach. Functional status was measured with the FIM instrument and the Modified Barthel Index. RESULTS: The TUG and 2MWT scores differed significantly in groups of patients using different ambulatory aids ($P=.006$), whereas no such difference was observed for the functional reach ($P=.40$). The correlations between the TUG test and FIM and between the 2MWT and FIM were $-.59$ and $.59$ ($P<.001$), respectively, at admission, and $-.42$ and $.47$ ($P< \text{or} =.04$), respectively, at admission and discharge. The correlations between functional reach and the FIM were not significant ($P> \text{or} =.09$). Standardized response means were 1.1 for the TUG, 0.7 for the 2MWT, and 0.5 for functional reach. CONCLUSIONS: The TUG test and 2MWT are valid and responsive outcome measures in older persons participating in geriatric

rehabilitation. Functional reach was a moderately responsive outcome measure but did not consistently reflect ambulatory or functional status.

Burnett J, Dyer CB, Naik AD. **Convergent validation of the Kohlman Evaluation of Living Skills as a screening tool of older adults' ability to live safely and independently in the community.** *Arch Phys Med Rehabil.* 2009 Nov;90(11):1948-52.

Notes: Validation study of the Kohlman Evaluation of Living Skills (KELS), showing its correlation with a variety of physical function and cognitive function measures. Proposed for use as screening tool to identify ability of older adults to live independently.

Abstract: **OBJECTIVE:** To evaluate the convergent validity of the Kohlman Evaluation of Living Skills (KELS) to screen older adults' ability to live safely and independently. **DESIGN:** Cross-sectional study correlating KELS with components of a Comprehensive Geriatric Assessment. **SETTING:** Participants' homes. **PARTICIPANTS:** Community-dwelling older adults (N=200) 65 years and older including 100 persons referred by Adult Protective Services (APS) and 100 ambulatory patients matched on age, race, sex, and socioeconomic status. **INTERVENTIONS:** In-home comprehensive assessment. **MAIN OUTCOME MEASURES:** KELS, Geriatric Depression Scale (GDS), modified Physical Performance Test (mPPT), Mini-Mental State Examination (MMSE), Knee Extensor Break Test, Executive Cognitive Test (EXIT25), executive clock-drawing test (CLOX) 1 and 2, and an 8-foot walk test. **RESULTS:** Older adults with abnormal KELS scores performed significantly worse on all tests except for the Knee Extensor Break Test. Accordingly, among the entire group, the KELS correlated with measures of executive function (EXIT25, $r=.705$, $P<.001$; CLOX 1, $r=-.629$, $P<.001$), cognitive function (MMSE, $r=-.508$, $P<.001$), affect (GDS, $r=.318$, $P<.001$), and physical function (mPPT, $r=-.472$, $P<.001$) but did not correlate with the Knee Extensor Break Test ($r=-.068$, $P=.456$). Among those referred by APS, the KELS failed to correlate with only the 8-foot walk test ($r=.175$, $P=.153$) and GDS ($r=.080$, $P=.450$). **CONCLUSIONS:** This study demonstrated the convergent validity of KELS with a battery of cognitive, affective, executive, and functional measures often used to determine older adults' ability to live safely and independently in the community. KELS may be a valid and pragmatic alternative to screen for the capacity to live safely and independently among older adults.

Cohen HJ, Feussner JR, Weinberger M, et al. **A controlled trial of inpatient and outpatient geriatric evaluation and management.** *N Engl J Med.* 2002 Mar 21;346(12):905-12.

Notes: Multicenter RCT (n=1388) of inpatient followed by outpatient geriatric evaluation in frail older hospitalized pts .

Abstract: **BACKGROUND:** Over the past 20 years, both inpatient units and outpatient clinics have developed programs for geriatric evaluation and management. However, the effects of these interventions on survival and functional status remain uncertain. **METHODS:** We conducted a randomized trial involving frail patients 65 years of age or older who were hospitalized at 11 Veterans Affairs medical centers. After their condition had been stabilized, patients were randomly

assigned, according to a two-by-two factorial design, to receive either care in an inpatient geriatric unit or usual inpatient care, followed by either care at an outpatient geriatric clinic or usual outpatient care. The interventions involved teams that provided geriatric assessment and management according to Veterans Affairs standards and published guidelines. The primary outcomes were survival and health-related quality of life, measured with the use of the Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36), one year after randomization. Secondary outcomes were the ability to perform activities of daily living, physical performance, utilization of health services, and costs. RESULTS: A total of 1388 patients were enrolled and followed. Neither the inpatient nor the outpatient intervention had a significant effect on mortality (21 percent at one year overall), nor were there any synergistic effects between the two interventions. At discharge, patients assigned to the inpatient geriatric units had significantly greater improvements in the scores for four of the eight SF-36 subscales, activities of daily living, and physical performance than did those assigned to usual inpatient care. At one year, patients assigned to the outpatient geriatric clinics had better scores on the SF-36 mental health subscale, even after adjustment for the score at discharge, than those assigned to usual outpatient care. Total costs at one year were similar for the intervention and usual-care groups. CONCLUSIONS: In this controlled trial, care provided in inpatient geriatric units and outpatient geriatric clinics had no significant effects on survival. There were significant reductions in functional decline with inpatient geriatric evaluation and management and improvements in mental health with outpatient geriatric evaluation and management, with no increase in costs.

Crooks V, Waller S, Smith T, Hahn TJ. **The use of the Karnofsky Performance Scale in determining outcomes and risk in geriatric outpatients.** *J Gerontol.* 1991 Jul;46(4):M139-44.

Notes: Validation of Karnofsky Performance Scale for use as assessment of functional status and as a predictor of adverse outcome, among ambulatory geriatric patients.

Abstract: The Karnofsky Performance Scale (KPS) was evaluated in a geriatric outpatient population with regard to three issues: its strength of association with widely used and validated geriatric instruments; its ability to predict patient outcomes; and its ability to serve as an identifier of high-risk patients. The 134-patient sample was given a comprehensive geriatric assessment which included the KPS, the Activities of Daily Living (ADL) scale, the Instrumental Activities of Daily Living (IADL) scale, and other psychosocial and sensory tests. The KPS, ADL, and IADL were significantly correlated with each other, and the KPS showed the strongest associations with other functional measures. The KPS was also highly predictive of outcomes, performing better or equally well as the ADL and IADL. The KPS designation of high- and low-risk groups resulted in statistically significant score differences between groups in all but one assessment area, demonstrating better ability to discriminate than either the ADL or IADL. Thus, the KPS was shown to serve as an effective proxy score for a patient's health and functional status. It also was a significant predictor of hospitalizations, survival time, community residence, and institutionalization. Finally, the KPS was shown to adequately distinguish risk groups to aid in the targeting of services to ambulatory geriatric patients.

*Guralnik JM, Simonsick EM, Ferrucci L, et al. **A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission.** *J Gerontol Med Sci* 1994; 49(2):M85-M94

Abstract: BACKGROUND: A short battery of physical performance tests was used to assess lower extremity function in more than 5,000 persons age 71 years and older in three communities. METHODS: Balance, gait, strength, and endurance were evaluated by examining ability to stand with the feet together in the side-by-side, semi-tandem, and tandem positions, time to walk 8 feet, and time to rise from a chair and return to the seated position 5 times. RESULTS: A wide distribution of performance was observed for each test. Each test and a summary performance scale, created by summing categorical rankings of performance on each test, were strongly associated with self-report of disability. Both self-report items and performance tests were independent predictors of short-term mortality and nursing home admission in multivariate analyses. However, evidence is presented that the performance tests provide information not available from self-report items. Of particular importance is the finding that in those at the high end of the functional spectrum, who reported almost no disability, the performance test scores distinguished a gradient of risk for mortality and nursing home admission. Additionally, within subgroups with identical self-report profiles, there were systematic differences in physical performance related to age and sex. CONCLUSION: This study provides evidence that performance measures can validly characterize older persons across a broad spectrum of lower extremity function. Performance and self-report measures may complement each other in providing useful information about functional status.

Jette AM, Davies AR, Cleary PD, et al. **The Functional Status Questionnaire: reliability and validity when used in primary care.** *J Gen Intern Med.* 1986 May-Jun;1(3):143-9.

Abstract: A comprehensive functional assessment requires thorough and careful inquiry, which is difficult to accomplish in most busy clinical practices. This paper examines the reliability and validity of the Functional Status Questionnaire (FSQ), a brief, standardized, self-administered questionnaire designed to provide a comprehensive and feasible assessment of physical, psychological, social and role function in ambulatory patients. The FSQ can be completed and computer-scored in minutes to produce a one-page report which includes six summated-rating scale scores and six single-item scores. The clinician can use this report both to screen for and to monitor patients' functional status. In this study, the FSQ was administered to 497 regular users of Boston's Beth Israel Hospital's Healthcare Associates and 656 regular users of 76 internal medicine practices in Los Angeles. The data demonstrate that the FSQ produces reliable sub-scales with construct validity. The authors believe the FSQ addresses many of the problems behind the slow diffusion into primary care of systematic functional assessment.

Jette AM, Haley SM, and Ni Pengsheng. **Comparison of Functional Status Tools Used in Post-Acute Care.** *Health Care Financing Review* 2003 Spring 24(3):13-24.

Abstract: There is a growing health policy mandate for comprehensive monitoring of functional outcomes across post-acute care (PAC) settings. This article presents an empirical comparison of four functional outcome instruments used in PAC with respect to their content, breadth of coverage, and measurement precision. Results illustrate limitations in the range of content, breadth of coverage, and measurement precision in each outcome instrument. None appears well-equipped to meet the challenge of monitoring quality and functional outcomes across settings where PAC is provided. Limitations in existing assessment methodology has stimulated the development of more comprehensive outcome assessment systems specifically for monitoring the quality of services provided to PAC patients.

Kono A, Kai I, Sakato C, Rubenstein LZ. **Frequency of going outdoors: a predictor of functional and psychosocial change among ambulatory frail elders living at home.** *J Gerontol A Biol Sci Med Sci.* 2004 Mar;59(3):275-80.

Notes: Validation of assessing frequency of "going outdoors" as a predictor of decline in ability to perform ADLs in a group of frail older adults (n=112).

Abstract: **BACKGROUND:** This study investigated the relationship between the frequency of going outdoors among ambulatory frail elders living at home and subsequent functional and psychosocial changes. **METHODS:** In this 9-month prospective cohort study, data were collected via questionnaire from 112 frail elderly persons living at home and their families. Functional and psychosocial status at baseline and follow-up regarding activities of daily living, functional capacity, depression, self-efficacy for daily activities, self-efficacy for health promotion, and social support, were compared among 3 groups defined by the frequency of going outdoors: 1) more than 4 times a week, 2) 1-3 times a week, 3) less than once a week. At baseline, elders going outdoors more often were less functionally impaired, more socially active, and scored less depressed than elders going outdoors less often. **RESULTS:** There were significant differences in functional capacity ($p=.0201$) and intellectual activities ($p=.0026$) over time according to the frequency of going outdoors, even when controlling for baseline differences, and the scores of those who seldom went outdoors decreased rapidly. There were similar relationships between frequency of going outdoors and changes in self-efficacy for both daily activities ($p=.0067$) and for health promotion ($p=.0245$), with participants going outdoors most frequently improving significantly more. **CONCLUSIONS:** These results suggest that the frequency of going outdoors may be a useful and simple indicator to predict changes in functional capacity, intellectual activity and self-efficacy.

*McCarten JR, Anderson P, Kuskowski MA, et al. **Finding dementia in primary care: the results of a clinical demonstration project.** *J Am Geriatr Soc.* 2012 Feb;60(2):210-7

Abstract: **OBJECTIVES:** To assess the effect of screening on diagnosing cognitive impairment. **DESIGN:** Quality improvement initiative. **SETTING:** Seven Veterans Affairs Medical Centers. **PARTICIPANTS:** Veterans aged 70 or older without a prior diagnosis of cognitive impairment.

MEASUREMENTS: Veterans failing a brief cognitive screen (Mini-Cog score <4/5) at a routine primary care visit were offered a further, comprehensive evaluation with an advance practice registered nurse trained in dementia care and integrated into the primary care clinic. Veterans completing the evaluation were reviewed in a consensus conference and assigned a diagnosis of dementia; cognitive impairment, no dementia; or no cognitive impairment. Total numbers of screens, associated scores (0-5), and the consensus diagnoses were tallied. New cognitive impairment diagnoses were also tracked for veterans who passed the screen but requested further evaluation, failed but declined further evaluation, or were not screened. Primary care provider satisfaction with the program also was assessed. RESULTS: Of 8,342 veterans offered screening, 8,063 (97%) accepted, 2,081 (26%) failed the screen, 580 (28%) agreed to further evaluation, and 540 (93%) were diagnosed with cognitive impairment, including 432 (75%) with dementia. For screen passes requesting further evaluation, 87% (103/118) had cognitive impairment, including 70% (82/118) with dementia. Screen failures declining further evaluation had 17% (259/1,501) incident cognitive impairment diagnosed through standard care, bringing the total newly documented cognitive impairment in all screens to 11% (902/8,063), versus 4% (1,242/28,349) in similar clinics without this program. Eighty-two percent of primary care providers in clinics with this program agreed that it provided a useful service. CONCLUSION: Screening combined with offering further evaluation increased new diagnoses of cognitive impairment in older veterans two to three times. Veterans accepted screening well, and providers found the program useful."

McHorney CA, Cohen AS. **Equating health status measures with item response theory: illustrations with functional status items.** *Med Care.* 2000 Sep;38(9 Suppl):1143-59.

Notes: Utilizing item response theory, elements from different functional status instruments were equated.

Abstract: BACKGROUND: More than 75 instruments have been developed to measure functional status. These measures differ in number of items, type of rating scale, and item difficulty. Such variations render it impossible to compare data across different measures. One way to overcome such test dependency is test equating, which relates scores from different measures to a common metric. OBJECTIVE: We developed a bank of physical functioning items and equated them using item response theory. DESIGN: We used a common-item equating design and a self-administered survey of functional status. SUBJECTS: Individuals > or = 65 years of age who had > or = 1 ambulatory visit across a 3-month sampling frame to a Veterans Administration Medical Center or its affiliated university medical center. RESULTS: The dressing items were the most discriminating, followed by bathing, toileting, mobility, cooking/eating, and household and community activities. The 5 most discriminating items were to put underclothes on, manage clothes after toileting, move between rooms, take pants/slacks off, and get into bed. Most of the items were located on the easier end of the ability continuum. Only 6 would classify as being very difficult. CONCLUSIONS: We used item response theory to equate and calibrate a large number of activities of daily living on the same scale; by doing so, we were able to better understand the structure and order of domain-specific items to each other, as well as the interrelations among items across the ability continuum.

*Miller DK, Wolinsky FD, Andresen EM, Malmstrom TK, Miller JP. **Adverse outcomes and correlates of change in the Short Physical Performance Battery over 36 months in the African American health project.** *J Gerontol A Biol Sci Med Sci.* 2008 May;63(5):487-94.

Abstract: BACKGROUND: The Short Physical Performance Battery (SPPB) is a well-established measure of lower body physical functioning in older persons but has not been adequately examined in African Americans or younger persons. Moreover, factors associated with changes in SPPB over time have not been reported. METHODS: A representative sample of 998 African Americans (49-65 years old at baseline) living in St. Louis, Missouri were followed for 36 months to examine the predictive validity of SPPB in this population and identify factors associated with changes in SPPB. SPPB was calibrated to this population, ranged from 0 (worst) to 12 (best), and required imputation for about 50% of scores. Adverse outcomes of baseline SPPB included death, nursing home placement, hospitalization, physician visits, incident basic and instrumental activity of daily living disabilities, and functional limitations. Changes in SPPB over 36 months were modeled. RESULTS: Adjusted for appropriate covariates, weighted appropriately, and using propensity scores to address potential selection bias, baseline SPPB scores were associated with all adverse outcomes except physician visits, and were marginally associated with hospitalization. Declines in SPPB scores were associated with low falls efficacy ($b = -1.311$), perceived income adequacy (-0.121), older age (-0.073 per year), poor vision (-0.754), diabetes mellitus (-0.565), refusal to report household income (1.48), ever had Medicaid insurance (-0.610), obesity (-0.437), hospitalization in the prior year (-0.521), and kidney disease ($-.956$). CONCLUSIONS: The effect of baseline SPPB on adverse outcomes in this late middle-age African American population confirms reports involving older, primarily white participants. Alleviating deterioration in lower body physical functioning guided by the associated covariates may avoid or delay multiple age-associated adverse outcomes.

Miller DR, Clark JA, Rogers WH, Skinner KM, et al. **The influence of place of administration on health-related quality-of-life assessments: findings from the Veterans Health Study.** *J Ambul Care Manage.* 2005 Apr-Jun;28(2):111-24.

Notes: Veterans Health study cohort ($n=304$) demonstrating how scoring on SF-36 can depend on location of administration (home versus clinic).

Abstract: Patient-based assessments of functional status and well-being, such as the short form survey (SF-36) developed in the Medical Outcomes Study, are increasingly used to monitor patient health status and the effects of medical care. Although they have been used in many populations under a variety of circumstances, little is known about how environmental factors, such as place of administration, influence patients' responses. We administered the SF-36 as part of comprehensive quality-of-life assessments to 304 participants in the pilot phase of the Veterans Health Study, a large observational study of health outcomes in VA ambulatory care. SF-36 questionnaires were self-administered twice by patients, once at home and again as part of an interview in a clinic setting. For most participants, less than a week passed between the 2 administrations. Scores from these questionnaires were compared as a measure of reliability and of the possible influence of place of

administration. Questionnaires self-administered at the time of the interview yielded mean scores that were significantly ($P < .05$) higher across all 8 SF-36 scales (physical function, role function with physical and emotional limitations, vitality, bodily pain, social function, mental health, general health perceptions) and both the physical and mental component summary scales. With scores scaled from 0 to 100, differences ranged from 2.1 (bodily pain) to 5.7 (role limitations due to emotional problems). Mean physical function was 56.8 at the time of the interview, and 52.4 at home. Higher scores from questionnaires administered at interview outnumbered lower scores by 3 to 2 for most scales. These differences remained even after restricting the sample to those with the highest cognitive function scores and the shortest interval between administrations. Because selection factors and order of administration could not be completely dismissed, a large number of other administrative, clinical, and sociodemographic factors were examined, which, however, failed to provide adequate explanation for these differences. Careful consideration should be given concerning the physical and social environment in the administration of health-related quality-of-life assessments. Findings from this study suggest that more favorable measures of self-reported functional status and well-being may be expected from clinic administrations of instruments.

Min L, Yoon W, Mariano J, et al. **The vulnerable elders-13 survey predicts 5-year functional decline and mortality outcomes in older ambulatory care patients.** *J Am Geriatr Soc.* 2009 Nov;57(11):2070-6. Epub 2009 Sep 28.

Notes: Validation of the Vulnerable Elders-13 Survey (VES-13) tool among community dwelling adults aged 75 years and older ($n=649$), showing it predicts functional decline and mortality outcomes.

Abstract: OBJECTIVES: To test the predictive properties of the Vulnerable Elders-13 Survey (VES-13) a short tool that predicts functional decline and mortality over a 1- to 2-year follow-up interval over a 5-year interval. DESIGN: Longitudinal evaluation with mean follow-up of 4.5 years. SETTING: Two managed-care organizations. PARTICIPANTS: Six hundred forty-nine community-dwelling older adults ($> \text{ or } = 75$) enrolled in the Assessing Care of Vulnerable Elders observational study who screened positive for symptoms of falls or fear of falling, bothersome urinary incontinence, or memory problems. MEASUREMENTS: VES-13 score (range 1-10, higher score indicates worse prognosis), functional decline (decline in count of 5 activities of daily living or nursing home entry), and deaths. RESULTS: Higher VES-13 scores were associated with greater predicted probability of death and decline in older patients over a mean observation period of 4.5 years. For each additional VES-13 point, the odds of the combined outcome of functional decline or death was 1.37 (95% confidence interval (CI)=1.25-1.50), and the area under the receiver operating curve was 0.75 (95% CI=0.71-0.80). In the Cox proportional hazards model predicting time to death, the hazard ratio was 1.23 (95% CI=1.19-1.27) per additional VES-13 point. CONCLUSION: This study extends the utility of the VES-13 to clinical decisions that require longer-term prognostic estimates of functional status and survival.

*Oh B, Cho B, Choi HC, Son KY, Park SM, Chun S, Cho SI. **The influence of lower-extremity function in elderly individuals' quality of life (QOL): an analysis of the correlation between SPPB and EQ-5D.** *Arch Gerontol Geriatr.* 2014 Mar-Apr;58(2):278-82. doi: 10.1016/j.archger.2013.10.008. Epub 2013 Nov 2.

Abstract: BACKGROUND: If an association between a decline in physical performance and subjective QOL is confirmed, the SPPB could be used as a predictor for declining QOL in older people. OBJECTIVE: This study aimed to elucidate the association between the short physical performance battery (SPPB) and QOL (EQ-5D) to determine the utility of the SPPB as a predictor of declining QOL. METHODS: The SPPB and the EQ-5D test were performed with a random sample of participants nested in the Korean Longitudinal Study of Aging (KLoSA) panel. Comparisons of the adjusted mean scores on the EQ-5D index between normal and abnormal SPPB groups were performed. We selected the quartiles of the EQ-5D index variables for the analysis. The association between the EQ-5D index and SPPB abnormality was examined using multinomial logistic regression analysis. Additionally, the associations between gait speed and chair stand time and the EQ-5D index were examined using the same analysis. RESULTS: Four hundred and twenty-two subjects were included in the analysis. The adjusted means for the EQ-5D index were significantly lower when the SPPB score was abnormal ($p=0.022$ for men, $p=0.047$ for women). An abnormal SPPB score was significantly associated with the lowest quartile of EQ-5D index score (adjusted OR 3.54 in the lowest quartile for men; adjusted OR 2.50 and 3.37 in the lowest and second quartiles for women). Gait speed was significantly associated with the EQ-5D index for participants of both sexes, but standup time was associated with the EQ-5D index only for men. CONCLUSIONS: An abnormal SPPB score was associated with lower QOL. Thus, the SPPB has the potential to be used as an early predictor of declining QOL in clinical settings and epidemiological studies.

*Patel MS, Mohan D, Andersson YM, Baz M, Kon SS, Canavan JL, Jackson SG, Clark AL, Hopkinson NS, Natanek SA, Kemp PR, Bruijnzeel PL, Man WD, Polkey MI. **Phenotypic characteristics associated with reduced short physical performance battery score in COPD.** *Chest.* 2014 May;145(5):1016-24. 2013 Dec 12 doi: 10.1378/chest.13-1398. [Epub ahead of print]

Abstract: BACKGROUND: The Short Physical Performance Battery (SPPB) is commonly used in gerontology, but its determinants have not been previously evaluated in COPD. In particular, it is unknown whether pulmonary aspects of COPD would limit the value of SPPB as an assessment tool of lower limb function. METHODS: In 109 patients with COPD, we measured SPPB score, spirometry, 6-min walk distance, quadriceps strength, rectus femoris cross-sectional area, fat-free mass, physical activity, health status, and Medical Research Council dyspnea score. In a subset of 31 patients with COPD, a vastus lateralis biopsy was performed, and the biopsy specimen was examined to evaluate the structural muscle characteristics associated with SPPB score. The phenotypic characteristics of patients stratified according to SPPB were determined. RESULTS: Quadriceps strength and 6-min walk distance were the only independent predictors of SPPB score in a multivariate regression model. Furthermore, while age, dyspnea, and health status were also univariate predictors of SPPB score, FEV 1 was not. Stratification by reduced SPPB score identified patients with locomotor muscle atrophy and increasing impairment in strength, exercise capacity, and daily physical activity. Patients with mild or major impairment defined as an SPPB score < 10 had a higher proportion of type 2

fibers (71% [14] vs 58% [15], $P = .04$). **CONCLUSIONS:** The SPPB is a valid and simple assessment tool that may detect a phenotype with functional impairment, loss of muscle mass, and structural muscle abnormality in stable patients with COPD.

Siu AL, Reuben DB, Hays RD. **Hierarchical measures of physical function in ambulatory geriatrics.** *J Am Geriatr Soc.* 1990 Oct;38(10):1113-9.

Abstract: Brief and uncomplicated methods for obtaining information on functional status would facilitate the assessment of older patients. We evaluated the potential usefulness, reliability, and validity of four hierarchical measures of physical function in 123 elderly subjects seen in four ambulatory geriatrics settings. Although the vast majority (83.2%) of subjects were fully independent on the Katz Activities of Daily Living Scale, a broader scope of functional difficulty was reported on the Spector-Katz, five-item OARS, and Rosow-Breslau scales. The three scales all had either borderline or more acceptable coefficients of scalability (0.57-0.77); the hierarchical order of items was not observed in 5.3% to 13.6% of subjects. Combining items from these established measures resulted in two new scales with acceptable scalability and construct validity; however, some errors in item order persisted. Although their ease of administration is clearly advantageous, clinicians using short hierarchical scales to assess functional status of older patients should be aware of their limitations.

Thomas DR, Marren K, Banks W, Morley J. **Do objective measurements of physical function in ambulatory nursing home women improve assessment of functional status?** *J Am Med Dir Assoc.* 2007 Sep;8(7):469-76. Epub 2007 Aug 13.

Notes: Observational cohort study of ambulatory femal adults in nursing homes, demonstrating correlation between gait speed (six minute walk) and functional status.

Abstract: **OBJECTIVE:** To compare the functional status of ambulatory women in four academic nursing homes using standardized rating scales and physical performance measures used in community settings. **DESIGN:** Observational cohort. **PARTICIPANTS:** Women older than 65 years, ambulatory with or without an assistive device. **INTERVENTIONS:** Direct comparison of the Functional Independence Measure and the Performance Self Maintenance Score with objective measure of the Get-up-and-go test, a six minute walk, and a six meter walk. **RESULTS:** Two variables, the gait speed and creatinine clearance, correctly classified 80% of subjects with higher functional status defined by subjective rating scales. **CONCLUSION:** Although gait speed calculated by a six meter walk is easily performed and highly correlated with subjectively assessed functional status, the majority of these ambulatory women nursing home residents exceeded the population means for each of the performance-based physical function measures.

*Veronese N, Bolzetta F, Toffanello ED, Zambon S, De Rui M, Perissinotto E, Coin A, Corti MC, Baggio G, Crepaldi G, Sergi G, Manzato E. **Association between short physical performance battery and falls in older people: the PRO.V.A. study.** *Rejuvenation Res.* 2014 Jan 6. [Epub ahead of print]

Abstract: It is known that weakness in the lower limbs is associated with recurrent falls in old people. Among the tests routinely used to assess lower extremity strength, the Short Physical Performance Battery (SPPB) is one of those used most often, but its relationship with recurrent falls is poorly investigated. We aimed to determine if SPPB scores are related to recurrent falling in a sample of 2710 older-aged people, and to ascertain which test in the SPPB is most strongly associated with a higher rate of falls. In this cross-sectional study, we demonstrated that participants scoring 0-6 in the SPPB were more likely to be recurrent fallers than those scoring 10-12 (odds ratio [OR]=3.46, 95% confidence interval [CI] 2.04-5.88 in women; OR=3.82, 95% CI 1.77- 8.52, in men). SPPB scores of 7-9 were only associated with women being more likely to be recurrent fallers (OR=2.03, 95% CI 1.28-3.22). When the SPPB items were analyzed separately, even a lower score in gait speed for women was significantly associated with the presence of recurrent falls (OR=2.11; 95% CI 1.04-4.30), whereas in men only a significant increase in the time taken to complete the five timed chair stands test was associated with a higher rate of falls (OR=2.75; 95% CI 1.21-6.23). In conclusion, our study demonstrated that SPPB scores ≤ 6 are associated with a higher fall rate in old people of both genders; in females, even an SPPB score between 7 and 9 identifies subjects at a higher likelihood of being recurrent fallers. Among the single items of the SPPB, the most strongly associated with falls were gait speed in women and the five timed chair stands test in men.

Yarnold PR, Bryant FB, Repasy AB, Martin GJ. **The factor structure and cross-sectional distributional properties of the Beth Israel/UCLA Functional Status Questionnaire.** *J Behav Med.* 1991 Apr;14(2):141-53.

Abstract: The functional status of ambulatory patients is an important correlate of their emotional and physical well-being and is subject to influence by the delivery of health care. First, the present study obtains a profile on the FSQ for a large sample of young, healthy adults (N = 508 college undergraduates), for use as an "empirical standard" against which to evaluate the effect of disease or injury on an individual's functional status. Second, cross-sectional analyses contrast distributional features of responses to the FSQ between (a) the present younger, healthy sample and (b) a previously published, older ambulatory patient sample. These analyses suggest that the FSQ has acceptable discriminant validity for intergroup comparisons. Finally, confirmatory structural analyses suggest that the theoretical six-factor model hypothesized to underlie responses to the FSQ has a modest, yet acceptable, goodness of fit to actual data.

Yarnold PR, Stille FC, Martin GJ. **Cross-sectional psychometric assessment of the Functional Status Questionnaire: use with geriatric versus nongeriatric ambulatory medical patients.** *Int J Psychiatry Med.* 1995;25(4):305-17.

Abstract: OBJECTIVE: The Beth Israel/UCLA Functional Status Questionnaire (FSQ) is a multidimensional self-report instrument used for assessing the physical, social, and psychological status of children and adults. This study assessed the appropriateness of the FSQ for use with geriatric (at least 65 years of age) ambulatory medical patients. METHOD: Concurrent cohort

convenience samples of forty geriatric and eighty-five nongeriatric ambulatory patients were drawn from a general internal medicine clinic. Patients completed the FSQ while waiting to see their physician. Analyses were conducted in order to: 1) address the magnitude and pattern of missing responses that are generated when the FSQ is administered to small groups; 2) assess whether, as was intended, each of the different FSQ subscales is unidimensional; 3) evaluate the magnitude and pattern of variances and covariances of items constituting FSQ subscales; 4) compare profiles of FSQ scores between geriatric versus nongeriatric samples; and 5) investigate whether FSQ subscales correlate with different self-report outcome measures in a convergent or divergent manner.

RESULTS: For both samples, FSQ subscales were internally consistent and moderately variable. Cross-sectional comparisons revealed both convergent and divergent relationships between FSQ subscales and measures of social support and satisfaction with health. **CONCLUSIONS:** The FSQ appears to be appropriate for use with geriatric ambulatory medical patients. Findings highlighted the positive influence of intermediate activities of daily life--involving moderate levels of physical activity--on satisfaction with health, and the negative effect of depression on physical activity.

Interventions

Boult C, Boult LB, Morishita L, et al. **A randomized clinical trial of outpatient geriatric evaluation and management.** *J Am Geriatr Soc.* 2001 Apr;49(4):351-9.

Notes: RCT of outpatient geriatric evaluation and management in older ambulatory adults (n=568) showing slowing of functional decline.

Abstract: **OBJECTIVES:** To measure the effects of outpatient geriatric evaluation and management (GEM) on high-risk older persons' functional ability and use of health services. **DESIGN:** Randomized clinical trial. **SETTING:** Ambulatory clinic in a community hospital. **PARTICIPANTS:** A population-based sample of community-dwelling Medicare beneficiaries age 70 and older who were at high risk for hospital admission in the future (N = 568). **INTERVENTION:** Comprehensive assessment followed by interdisciplinary primary care. **MEASUREMENTS:** Functional ability, restricted activity days, bed disability days, depressive symptoms, mortality, Medicare payments, and use of health services. Interviewers were blinded to participants' group status. **RESULTS:** Intention-to-treat analysis showed that the experimental participants were significantly less likely than the controls to lose functional ability (adjusted odds ratio (aOR) = 0.67, 95% confidence interval (CI) = 0.47-0.99), to experience increased health-related restrictions in their daily activities (aOR = 0.60, 95% CI = 0.37-0.96), to have possible depression (aOR = 0.44, 95% CI = 0.20-0.94), or to use home healthcare services (aOR = 0.60, 95% CI = 0.37-0.92) during the 12 to 18 months after randomization. Mortality, use of most health services, and total Medicare payments did not differ significantly between the two groups. The intervention cost \$1,350 per person. **CONCLUSION:** Targeted outpatient GEM slows functional decline.

Hauer K, Rost B, Rüttschle K, et al. **Exercise training for rehabilitation and secondary prevention of falls in geriatric patients with a history of injurious falls.** *J Am Geriatr Soc.* 2001 Jan;49(1):10-20.

Notes: RCT of outpatient exercise training following admission to acute care or inpatient rehabilitation (n=57 female pts) shows improvement in functional performance.

Abstract: **OBJECTIVE:** To determine the safety and efficacy of an exercise protocol designed to improve strength, mobility, and balance and to reduce subsequent falls in geriatric patients with a history of injurious falls. **DESIGN:** A randomized controlled 3-month intervention trial, with an additional 3-month follow-up. **SETTING:** Out-patient geriatric rehabilitation unit. **PARTICIPANTS:** Fifty-seven female geriatric patients (mean age 82 +/- 4.8 years; range 75-90) admitted to acute care or inpatient rehabilitation with a history of recurrent or injurious falls including patients with acute fall-related fracture. **INTERVENTION:** Ambulatory training of strength, functional performance, and balance 3 times per week for 3 months. Patients of the control group attended a placebo group 3 times a week for 3 months. Both groups received an identical physiotherapeutic treatment 2 times a week, in which strengthening and balance training were excluded. **MEASUREMENTS:** Strength, functional ability, motor function, psychological parameters, and fall rates were assessed by standardized protocols at the beginning (T1) and the end (T2) of intervention. Patients were followed up for 3 months after the intervention (T3). **RESULTS:** No training-related medical problems occurred in the study group. Forty-five patients (79%) completed all assessments after the intervention and follow-up period. Adherence was excellent in both groups (intervention 85.4 +/- 27.8% vs control 84.2 +/- 29.3%). The patients in the intervention group increased strength, functional motor performance, and balance significantly. Fall-related behavioral and emotional restrictions were reduced significantly. Improvements persisted during the 3-month follow-up with only moderate losses. For patients of the control group, no change in strength, functional performance, or emotional status could be documented during intervention and follow-up. Fall incidence was reduced nonsignificantly by 25% in the intervention group compared with the control group (RR:0.753 CI:0.455-1.245). **CONCLUSIONS:** Progressive resistance training and progressive functional training are safe and effective methods of increasing strength and functional performance and reducing fall-related behavioral and emotional restrictions during ambulant rehabilitation in frail, high-risk geriatric patients with a history of injurious falls.

Means KM, Rodell DE, O'Sullivan PS, Cranford LA. **Rehabilitation of elderly fallers: pilot study of a low to moderate intensity exercise program.** *Arch Phys Med Rehabil.* 1996 Oct;77(10):1030-6.

Notes: Uncontrolled trial of exercise program in ambulatory adults (n=65) showing no significant improvement in falls or fall-related injuries.

Abstract: **OBJECTIVE:** The role of exercise in the prevention of falls and fall-related injuries among elderly persons is unclear. The objective of this study was to assess the response to an exercise-based rehabilitation program intended to improve balance and mobility and reduce or prevent falls. **DESIGN:** Pretest-posttest experimental design with repeated measures at baseline, immediately postintervention, and 6 months postintervention. To assess the effect of repeated exposure to our main outcome measure (the obstacle course), half of the participants (randomly selected) were

allowed to practice on the obstacle course. SETTING: A veterans affairs medical center. PARTICIPANTS: Elderly, ambulatory, community-dwelling volunteers recruited from among local outpatients at our medical center. INTERVENTION: Sixty-five volunteers completed a 6-week supervised low to moderate intensity program of stretching, postural control, endurance walking, and coordination exercises designed to improve balance and mobility. Participants were divided into 2 groups: 34 participants who did not practice on the obstacle course during their exercise program and 31 participants who practiced on the obstacle course in addition to their otherwise identical exercise program. MAIN OUTCOME MEASURES: Performance on a functionally oriented obstacle course and self-reported falls and fall-related injuries. RESULTS: No significant performance differences were found between the two groups. After intervention, mean qualitative obstacle course scores improved modestly (5%) and mean obstacle course completion time decreased by 15% from baseline. These postintervention pairwise performance differences were clinically important but not statistically significant. Relative to baseline levels, postintervention falls and injuries did not change significantly. CONCLUSIONS: Our exercise intervention may have the potential to improve functional performance. However, some modifications are necessary to enhance efficacy. The obstacle course may be a useful tool in the evaluation of elderly persons with balance and mobility impairment in the rehabilitation setting.

Snyder A, Colvin B, Gammack JK. **Pedometer use increases daily steps and functional status in older adults.** *J Am Med Dir Assoc.* 2011 Oct;12(8):590-4. Epub 2010 Oct 12.

Notes: Small uncontrolled study of older ambulatory adults (n=36) showing improvement in some measures of functional status using a pedometer-based motivational program.

Abstract: OBJECTIVE: The benefits of increased physical activity in adults of any age are many. It is hypothesized that wearing a pedometer can motivate older adults to increase and sustain a higher level of ambulatory activity and improve measures of functional status. DESIGN: A prospective observational walking program using pedometers, goal orientation, and educational materials. Participants were given pedometers with the screen covered to measure baseline steps. The pedometer screen was then uncovered for 4 weeks and participants encouraged to increase daily steps by 5% weekly. The pedometers were removed for 2 weeks and then returned with the screen covered to measure maintenance of activity. SETTING: Six senior-living facilities in the Saint Louis area. PARTICIPANTS: A total of 36 ambulatory adults aged 65 or older. MEASUREMENTS: The primary outcome measurement was average daily steps. Secondary outcomes included scores on the "Timed Up and Go," Tinetti Gait and Balance Evaluation, functional reach, 2-minute walking distance, 30-second leg-lift repetitions, grip strength, Geriatric Depression Scale (GDS), and Quality of Life Scale. RESULTS: The average number of daily steps increased from 2992 to 3670 over a 4-week period, a 22.7% increase (P = .035). The average daily steps were not sustained once the pedometer was removed for 2 weeks. The Timed Up and Go decreased from 12.1 to 11.2 seconds (P = .014), 30-second leg lifts increased from 22.7 to 26.3 repetitions (P < .001), and 2-minute walking distance improved from 313.7 to 330.3 feet (P = .014) at study completion. No improvement was seen in grip strength, functional reach, GDS, or quality of life. CONCLUSION: Pedometers are a

successful motivational tool to increase ambulatory activity in older adults with a secondary benefit in functional status measures.

Wagner EH, LaCroix AZ, Grothaus L, et al. **Preventing disability and falls in older adults: a population-based randomized trial.** *Am J Public Health.* 1994 Nov;84(11):1800-6.

Notes: RCT of intervention program (nurse visits) in ambulatory adults (n=1559) showed reduced incidence of declining functional status at 1 year, though by 2 years differences between groups narrowed.

Abstract: OBJECTIVES: Because preventing disability and falls in older adults is a national priority, a randomized controlled trial was conducted to test a multicomponent intervention program. METHODS: From a random sample of health maintenance organization (HMO) enrollees 65 years and older, 1559 ambulatory seniors were randomized to one of three groups: a nurse assessment visit and follow-up interventions targeting risk factors for disability and falls (group 1, n = 635); a general health promotion nurse visit (group 2, n = 317); and usual care (group 3, n = 607). Data collection consisted of a baseline and two annual follow-up surveys. RESULTS: After 1 year, group 1 subjects reported a significantly lower incidence of declining functional status and a significantly lower incidence of falls than group 3 subjects. Group 2 subjects had intermediate levels of most outcomes. After 2 years of follow-up, the differences narrowed. CONCLUSIONS: The results suggest that a modest, one-time prevention program appeared to confer short-term health benefits on ambulatory HMO enrollees, although benefits diminished by the second year of follow-up. The mechanisms by which the intervention may have improved outcomes require further investigation.

Reviews

*Cordell CB, Borson S, Boustani M, et al. **Alzheimer's Association recommendations for operationalizing the detection of cognitive impairment during the Medicare Annual Wellness Visit in a primary care setting.** *Alzheimers Dement.* 2013 Mar;9(2):141-50. doi: 10.1016/j.jalz.2012.09.011. Epub 2012 Dec 20.

Abstract: The Patient Protection and Affordable Care Act added a new Medicare benefit, the Annual Wellness Visit (AWV), effective January 1, 2011. The AWV requires an assessment to detect cognitive impairment. The Centers for Medicare and Medicaid Services (CMS) elected not to recommend a specific assessment tool because there is no single, universally accepted screen that satisfies all needs in the detection of cognitive impairment. To provide primary care physicians with guidance on cognitive assessment during the AWV, and when referral or further testing is needed, the Alzheimer's Association convened a group of experts to develop recommendations. The resulting Alzheimer's Association Medicare Annual Wellness Visit Algorithm for Assessment of Cognition includes review of patient Health Risk Assessment (HRA) information, patient observation, unstructured queries during the AWV, and use of structured cognitive assessment tools for both patients and informants. Widespread implementation of this algorithm could be the first step in

reducing the prevalence of missed or delayed dementia diagnosis, thus allowing for better healthcare management and more favorable outcomes for affected patients and their families and caregivers.

Dy SM, Pfoh ER, Salive ME, Boyd CM. **Health-related quality of life and functional status quality indicators for older persons with multiple chronic conditions.** *J Am Geriatr Soc.* 2013 Dec;61(12):2120-7. Epub 2013 Dec 9.

Notes: Review of quality indicators for QOL and functional status assessment, relevant to pts with multiple chronic conditions.

Abstract: OBJECTIVES: To explore central challenges with translating self-reported measurement tools for functional status and health-related quality of life (HRQOL) into ambulatory quality indicators for older people with multiple chronic conditions (MCCs). DESIGN: Review. SETTING: Sources including the National Quality Measures Clearinghouse and National Quality Forum were reviewed for existing ambulatory quality indicators relevant to functional status, HRQOL, and people with MCCs. PARTICIPANTS: Seven informants with expertise in indicators using functional status and HRQOL. MEASUREMENTS: Informant interviews were conducted to explore knowledge about these types of indicators, particularly usability and feasibility. RESULTS: Nine important existing indicators were identified in the review. For process, identified indicators addressed whether providers assessed functional status; outcome indicators addressed quality of life. In interviews, informants agreed that indicators using self-reported data were important in this population. Challenges identified included concerns about usability due to inability to discriminate quality of care adequately between organizations and feasibility concerns regarding high data collection burden, with a correspondingly low response rate. Validity was also a concern because evidence is mixed that healthcare interventions can improve HRQOL or functional status for this population. As a possible first step, a structural standard could be systematic collection of these measures in a specific setting. CONCLUSION: Although functional status and HRQOL are important outcomes for older people with MCCs, few relevant ambulatory quality indicators exist, and there are concerns with usability, feasibility, and validity. Further research is needed on how best to incorporate these outcomes into quality indicators for people with MCCs.

Iezzoni LI, Sc. M., and Greenberg MS. **Capturing and Classifying Functional Status Information in Administrative Databases.** *Health Care Financing Review* 2003 Spring 24(3): 61-76.

Abstract: The health care delivery system aims to improve the functioning of Americans, but little information exists to judge progress toward meeting this goal. Administrative data generated through running and overseeing health care delivery offer considerable information about diagnoses and procedures in coded formats comparable across settings of care. This article explores the issues raised when considering adding coded information about functional status to administrative databases throughout the health care system. The National Committee on Vital and Health Statistics (NCVHS) identified the International Classification of Functioning, Disability and Health (ICF) as the only viable code set for consistently reporting functional status.

*Lin JS, O'Connor E, Rossum RC, et al. **Screening for Cognitive Impairment in Older Adults: An Evidence Update for the U.S. Preventive Services Task Force.** *Ann Intern Med.* 2013;159:601-612.

Abstract: "OBJECTIVE: We conducted this systematic review to support the U.S. Preventive Services Task Force (USPSTF) in updating its recommendation on screening for cognitive impairment in older adults. Our review addresses five questions: 1) Does screening for cognitive impairment in community-dwelling older adults improve decisionmaking, patient, family/caregiver, or societal outcomes?; 2) What is the test performance of screening instruments to detect dementia or mild cognitive impairment (MCI) in community-dwelling older adult primary care patients?; 3) What are the harms of screening for cognitive impairment?; 4) Do interventions for early dementia or MCI in older adults improve decisionmaking, patient, family/caregiver, or societal outcomes?; and 5) What are the harms of interventions for cognitive impairment? DATA SOURCES: We reviewed 12 relevant existing systematic reviews; database searches through December 2012 in MEDLINE, PsycINFO, and the Cochrane Central Register of Controlled Trials; and additional searches for ongoing trials through ClinicalTrials.gov, World Health Organization International Clinical Trials Registry Platform, and Current Controlled Trials (ISRCTN Register). STUDY SELECTION: We conducted dual independent review of 16,179 abstracts and 1,190 articles against the specified inclusion criteria, including: screening instruments that could be delivered in primary care in 10 minutes or less by a clinician or self-administered in 20 minutes or less; diagnostic accuracy studies that used a reference standard; screening studies conducted in unselected community-dwelling older adults relevant to primary care in the United States; major pharmacologic and nonpharmacologic interventions in people with MCI or mild to moderate dementia; intervention trials of efficacy; or trials and large observational studies examining adverse effects. Data Synthesis: The Mini-Mental State Examination (k=25) is the most thoroughly studied instrument but is not available for use without cost. Publicly available instruments with adequate test performance to detect dementia include the Clock Drawing Test (k=7), Mini-Cog (k=4), Memory Impairment Screen (k=5), Abbreviated Mental Test (k=4), Short Portable Mental Status Questionnaire (k=4), Free and Cued Selective Reminding Test (k=2), 7-Minute Screen (k=2), and Informant Questionnaire on Cognitive Decline in the Elderly (k=5). Medications approved by the U.S. Food and Drug Administration for Alzheimer disease (k=58) and caregiver interventions (k=59) show a small benefit of uncertain clinical importance for patients and their caregivers. Small benefits are also limited by common adverse effects of cholinesterase inhibitors and limited availability of complex caregiver interventions. Although promising, cognitive stimulation (k=6) and exercise (k=10) have limited evidence to support their use in persons with mild to moderate dementia or mild cognitive impairment. Limitation: Limited studies in persons with dementia other than Alzheimer disease and sparse reporting of important health outcomes. Conclusion: Brief instruments to screen for cognitive impairment can adequately detect dementia, but there is no empirical evidence that screening improves decision making. Whether interventions for patients or their caregivers have a clinically significant effect in persons with earlier detected cognitive impairment is still unclear. Primary Funding Source: Agency for Healthcare Research and Quality."

*Pahor M, Guralnik JM, Ambrosius WT, et al. **Effect of Structured Physical Activity on Prevention of Major Mobility Disability in Older Adults: The LIFE Study Randomized Clinical Trial.** *JAMA.* 2014 May 27. doi: 10.1001/jama.2014.5616. [Epub ahead of print]

Abstract: IMPORTANCE: In older adults reduced mobility is common and is an independent risk factor for morbidity, hospitalization, disability, and mortality. Limited evidence suggests that physical activity may help prevent mobility disability; however, there are no definitive clinical trials examining whether physical activity prevents or delays mobility disability. OBJECTIVE To test the hypothesis that a long-term structured physical activity program is more effective than a health education program (also referred to as a successful aging program) in reducing the risk of major mobility disability. DESIGN, SETTING, AND PARTICIPANTS: The Lifestyle Interventions and Independence for Elders (LIFE) study was a multicenter, randomized trial that enrolled participants between February 2010 and December 2011, who participated for an average of 2.6 years. Follow-up ended in December 2013. Outcome assessors were blinded to the intervention assignment. Participants were recruited from urban, suburban, and rural communities at 8 centers throughout the United States. We randomized a volunteer sample of 1635 sedentary men and women aged 70 to 89 years who had physical limitations, defined as a score on the Short Physical Performance Battery of 9 or below, but were able to walk 400 m. INTERVENTIONS Participants were randomized to a structured, moderate-intensity physical activity program (n = 818) conducted in a center (twice/wk) and at home (3-4 times/wk) that included aerobic, resistance, and flexibility training activities or to a health education program (n = 817) consisting of workshops on topics relevant to older adults and upper extremity stretching exercises. MAIN OUTCOMES AND MEASURES: The primary outcome was major mobility disability objectively defined by loss of ability to walk 400 m. RESULTS Incident major mobility disability occurred in 30.1% (246 participants) of the physical activity group and 35.5% (290 participants) of the health education group (hazard ratio [HR], 0.82 [95% CI, 0.69-0.98], P = .03). Persistent mobility disability was experienced by 120 participants (14.7%) in the physical activity group and 162 participants (19.8%) in the health education group (HR, 0.72 [95% CI, 0.57-0.91]; P = .006). Serious adverse events were reported by 404 participants (49.4%) in the physical activity group and 373 participants (45.7%) in the health education group (risk ratio, 1.08 [95% CI, 0.98-1.20]). CONCLUSIONS AND RELEVANCE A structured, moderate-intensity physical activity program compared with a health education program reduced major mobility disability over 2.6 years among older adults at risk for disability. These findings suggest mobility benefits from such a program in vulnerable older adults.

End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support

Functional Status Technical Expert Panel Guideline Summary

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**Citations that are preceded by an asterisk are indicative of recommendation by a member of the Functional Status Technical Expert Panel, and as such were incorporated after UM-KECC's initial environmental scan.*

*U.S. Preventive Services Task Force (USPSTF): Screening for Cognitive Impairment in Older Adults

Group: U.S. Preventive Services Task Force (USPSTF)

Target population: Community-dwelling adults in the general primary care population who are older than 65 years and have no signs or symptoms of cognitive impairment

Link: <http://www.uspreventiveservicestaskforce.org/uspstf14/dementia/dementiafinalrs.pdf>

Date: 2003 (revised 2014)

Rating Scheme for the Strength of the Recommendations and Level of Evidence

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the Clinical Considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms
Level of Certainty	Description	
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.	
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as:</p> <ul style="list-style-type: none"> • The number, size, or quality of individual studies. • Inconsistency of findings across individual studies. • Limited generalizability of findings to routine primary care practice. • Lack of coherence in the chain of evidence. <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>	

Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> • The limited number or size of studies. • Important flaws in study design or methods. • Inconsistency of findings across individual studies. • Gaps in the chain of evidence. • Findings not generalizable to routine primary care practice. • Lack of information on important health outcomes. <p>More information may allow estimation of effects on health outcomes.</p>
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Major Recommendations

Recommendation Statement: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for cognitive impairment.

Grade: I statement (No Recommendation)

Risk Assessment: Increasing age is the strongest known risk factor for cognitive impairment. Other reported risk factors for cognitive impairment include cardiovascular risk factors (such as diabetes, tobacco use, hypercholesterolemia, and hypertension), head trauma, learning disabilities (such as Down syndrome), depression, alcohol abuse, physical frailty, low education level, low social support, and having never been married.

Screening Tests: Screening tests for cognitive impairment in the clinical setting generally include asking patients to perform a series of tasks that assess 1 or more cognitive domains (memory, attention, language, and visuospatial or executive functioning). The most widely studied instrument is the Mini-Mental State Examination.

Other instruments with more limited evidence include the Clock Draw Test, Mini-Cog, Memory Impairment Screen, Abbreviated Mental Test, Short Portable Mental Status Questionnaire, Free and Cued Selective Reminding Test, 7-Minute Screen, Telephone Interview for Cognitive Status, and Informant Questionnaire on Cognitive Decline in the Elderly.

Treatment: Pharmacologic treatments approved by the U.S. Food and Drug Administration include acetylcholinesterase inhibitors and memantine. Nonpharmacologic interventions include cognitive training, lifestyle behavioral interventions, exercise, educational interventions, and multidisciplinary care interventions. Some interventions focus on the caregiver and aim to improve caregiver morbidity and delay institutionalization of persons with dementia.

Balance of Benefits and Harms: The evidence on screening for cognitive impairment is lacking, and the balance of benefits and harms cannot be determined.

*U.S. Preventive Services Task Force (USPSTF): Screening for Depression in Adults

Group: U.S. Preventive Services Task Force (USPSTF)

Target population: Nonpregnant adults, including older adults

Link: <http://www.uspreventiveservicestaskforce.org/uspstf09/adultdepression/addeprrr.pdf>

Date: 2002 (revised 2009; current update in progress)

Rating Scheme for the Strength of the Recommendations and Level of Evidence

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the Clinical Considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms
Level of Certainty	Description	
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.	
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as:</p> <ul style="list-style-type: none"> • The number, size, or quality of individual studies. • Inconsistency of findings across individual studies. • Limited generalizability of findings to routine primary care practice. • Lack of coherence in the chain of evidence. <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>	

Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> • The limited number or size of studies. • Important flaws in study design or methods. • Inconsistency of findings across individual studies. • Gaps in the chain of evidence. • Findings not generalizable to routine primary care practice. • Lack of information on important health outcomes. <p>More information may allow estimation of effects on health outcomes.</p>
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Major Recommendations

Recommendation Statement # 1: The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow up.

Grade: B recommendation.

Risk Assessment: Persons at increased risk for depression are considered at risk throughout their lifetime. Groups at increased risk include persons with other psychiatric disorders, including substance misuse; persons with a family history of depression; persons with chronic medical diseases; and persons who are unemployed or of lower socioeconomic status. Also, women are at increased risk compared with men. However, the presence of risk factors alone cannot distinguish depressed patients from non-depressed patients.

Screening tests: Simple screening questions may perform as well as more complex instruments. Any positive screening test result should trigger a full diagnostic interview using standard diagnostic criteria.

Timing of Screening: The optimal interval for screening is unknown. In older adults, significant depressive symptoms are associated with common life events, including medical illness, cognitive decline, bereavement, and institutional placement in residential or inpatient settings.

Recommendation Statement # 2: The USPTF recommends against routinely screening adults for depression when staff-assisted depression care supports are not in place. There may be considerations that support screening for depression in an individual patient.

Grade: C recommendation.

Risk Assessment: Persons at increased risk for depression are considered at risk throughout their lifetime. Groups at increased risk include persons with other psychiatric disorders, including substance misuse; persons with a family history of depression; persons with chronic medical diseases; and persons who are unemployed or of lower socioeconomic status. Also, women are at increased risk compared with men. However, the presence of risk factors alone cannot distinguish depressed patients from non-depressed patients.

Balance of harms and benefits: Limited evidence suggests that screening for depression in the absence of staff-assisted depression care does not improve depression outcomes.

HIGN Clinical Guideline and Recommendations for Assessment of Physical Function

Group: Hartford Institute for Geriatric Nursing (HIGN)

Target population: Hospitalized Older Adults

Link: <http://www.guideline.gov/content.aspx?id=43918&search=functional+status>

Date: 2003 (revised 2012)

Rating Scheme for the Level of Evidence

Level I: Systematic reviews (integrative/meta-analyses/clinical practice guidelines based on systematic reviews)

Level II: Single experimental study (randomized controlled trials [RCTs])

Level III: Quasi-experimental studies

Level IV: Non-experimental studies

Level V: Care report/program evaluation/narrative literature reviews

Level VI: Opinions of respected authorities/consensus panels

Major Recommendations

Assessment Parameters

- Comprehensive functional assessment of older adults includes independent performance of basic activities of daily living (ADLs), social activities, or instrumental activities of daily living (IADLs), the assistance needed to accomplish these tasks, and the sensory ability, cognition, and capacity to ambulate (Campbell et al., 2004 [Level I]; Doran et al., 2006 [Level VI]; Freedman, Martin, & Schoeni, 2002 [Level I]; Kane & Kane, 2000 [Level VI]; Katz et al., 1963 [Level I]; Lawton & Brody, 1969 [Level IV]; Lightbody & Baldwin, 2002 [Level VI]; McCusker, Kakuma, & Abrahamowicz, 2002 [Level I]; Tinetti & Ginter, 1988 [Level I]).
 - Basic ADLs (bathing, dressing, grooming, eating, continence, transferring)
 - IADLs (meal preparation, shopping, medication administration, housework, transportation, accounting)
 - Mobility (ambulation, pivoting)
- Older adults may view their health in terms of how well they can function rather than in terms of disease alone. Strengths should be emphasized as well as needs for assistance (Depp & Jeste, 2006 [Level I]; Pearson, 2000 [Level VI]).
- The clinician should document baseline functional status and recent or progressive declines in function (Graf, 2006 [Level V]).
- Function should be assessed over time to validate capacity, decline, or progress (Applegate, Blass, & Franklin, 1990 [Level IV]; Callahan et al., 2002 [Level VI]; Kane & Kane, 2000 [Level VI]).
- Standard instruments selected to assess function should be efficient to administer and easy to interpret. They should provide useful practical information for clinicians and should be incorporated into routine history taking and daily assessments (Kane & Kane, 2000 [Level VI]; Kresevic et al., 1998 [Level VI]) (see the "Availability of Companion Documents" field for tools).
- Interdisciplinary communication regarding functional status, changes, and expected trajectory should be part of all care settings and should include the patient and family whenever possible (Counsell et al., 2000 [Level II]; Covinsky et al., 1998 [Level II]; Kresevic et al., 1998 [Level VI]; Landefeld et al., 1995 [Level II]).

Care Strategies

Strategies to Maximize Functional Status and to Prevent Decline

- Maintain individual's daily routine. Help to maintain physical, cognitive, and social function through physical activity and socialization. Encourage ambulation, allow flexible visitation including pets, and encourage reading the newspaper (Krešević & Holder, 1998 [Level VI]; Landefeld et al., 1995 [Level II]).
- Educate older adults, family, and formal caregivers on the value of independent functioning and the consequences of functional decline (Graf, 2006 [Level V]; Krešević & Holder, 1998 [Level VI]; Vass et al., 2005 [Level II]).
 - Physiological and psychological value of independent functioning.
 - Reversible functional decline associated with acute illness (Hirsch, 1990 [Level IV]; Sager & Rudberg, 1998 [Level II]).
 - Strategies to prevent functional decline: exercise, nutrition, pain management, and socialization (Krešević & Holder 1998 [Level VI]; Landefeld et al., 1995 [Level II]; Siegler, Glick, & Lee, 2002 [Level VI]; Tucker, Molsberger, & Clark, 2004 [Level VI]).
 - Sources of assistance to manage decline.
- Encourage activity including routine exercise, range of motion, and ambulation to maintain activity, flexibility, and function (Counsell et al., 2000 [Level II]; Landefeld et al., 1995 [Level II]; Pedersen & Saltin, 2006 [Level I]).
- Minimize bed rest (Bates-Jensen et al., 2004 [Level V]; Covinsky et al., 1998 [Level II]; Krešević & Holder, 1998 [Level VI]; Landefeld et al., 1995 [Level II]).
- Explore alternatives to physical restraints use (see the National Guideline Clearinghouse [NGC] summary of the Hartford Institute for Geriatric Nursing guideline Physical restraints and side rails in acute and critical care settings) (Krešević & Holder, 1998 [Level VI]; Covinsky et al., 1998 [Level II]).
- Judiciously use medications, especially psychoactive medications, in geriatric dosages (see the NGC summary of the Hartford Institute for Geriatric Nursing guideline Reducing adverse drug events in older adults) (Inouye et al., 1998 [Level III]).
- Assess and treat for pain (Covinsky et al., 1998 [Level II]).
- Design environments with handrails, wide doorways, raised toilet seats, shower seats, enhanced lighting, low beds, and chairs of various types and height (Cunningham & Michael, 2004 [Level I]; Krešević & Holder, 1998 [Level VI]).
- Help individuals regain baseline function after acute illnesses by using exercise, physical or occupational therapy consultation, nutrition, and coaching (Conn et al., 2003 [Level I]; Covinsky et al., 1998 [Level II]; Engberg et al., 2002 [Level II]; Forbes, 2005 [Level VI]; Hodgkinson, Evans, & Wood, 2003 [Level I]; Krešević et al., 1998 [Level VI]).

Strategies to Help Older Individuals Cope with Functional Decline

- Help older adults and family members determine realistic functional capacity with interdisciplinary consultation (Krešević & Holder, 1998 [Level VI]).
- Provide caregiver education and support for families of individuals when decline cannot be ameliorated in spite of nursing and rehabilitative efforts (Graf, 2006 [Level V]).
- Carefully document all intervention strategies and patient responses (Graf, 2006 [Level V]).
- Provide information to caregivers on causes of functional decline related to acute and chronic conditions (Covinsky et al., 1998 [Level II]).
- Provide education to address safety care needs for falls, injuries, and common complications. Short-term skilled care for physical therapy may be needed; long-term care settings may be required to ensure safety (Covinsky et al., 1998 [Level II]).
- Provide sufficient protein and caloric intake to ensure adequate intake and prevent further decline. Liberalize diet to include personal preferences (Edington et al., 2004 [Level II]; Landefeld et al., 1995 [Level II]).

- Provide caregiver support and community services, such as home care, nursing, and physical and occupational therapy services to manage functional decline (Covinsky et al., 1998 **[Level II]**; Graf, 2006 **[Level V]**).

HIGN Clinical Guideline for Function-focused care (FFC) interventions.

Group: Hartford Institute for Geriatric Nursing

Target population: Older Adults

Link: <http://www.guideline.gov/content.aspx?id=43942&search=functional+status>

Date: 2012

Rating Scheme for the Level of Evidence

Level I: Systematic reviews (integrative/meta-analyses/clinical practice guidelines based on systematic reviews)

Level II: Single experimental study (randomized controlled trials [RCTs])

Level III: Quasi-experimental studies

Level IV: Non-experimental studies

Level V: Care report/program evaluation/narrative literature reviews

Level VI: Opinions of respected authorities/consensus panels

Major Recommendations

Function-focused Care (FFC) Interventions

- *Hospital care systems and processes*
 - Evaluation of leadership commitment to rehabilitative values (Boltz, Capezuti, & Shabbat, 2011 [Level IV]; Resnick, 2004 [Level VI]).
 - Interdisciplinary rounds that address functional assessment (baseline and current), evaluate potentially restrictive devices and agents, and yield a plan for progressive mobility (McVey et al., 1989 [Level II]).
 - Well-defined roles, including areas of accountability for assessment and follow-through for function-promoting activities (Jacelon, 2004 [Level IV]; Resnick et al., 2011 [Level III]).
 - Method of evaluating communication of patient needs among staff (Boltz, Capezuti, & Shabbat, 2011 [Level IV]).
 - Process of disseminating data (e.g., compliance with treatment plans and functional outcomes) (Boltz, Capezuti, & Shabbat, 2011 [Level IV]).
- *Policy and procedures to support function promotion*
 - Protocols that minimize adverse effects of selected procedures (e.g., urinary catheterization) and medications (e.g., sedative-hypnotic agents) contribute to positive functional outcomes (Kleinpell, 2007 [Level V]).
 - Supporting policies: identification and storage of sensory (e.g., glasses, hearing aids/amplifiers) and mobility devices and other assistive devices (Boltz, Capezuti, & Shabbat, 2011 [Level IV]; St. Pierre, 1998 [Level V]).
 - Discharge policies that address the continuous plan for function promotion (Boltz, Capezuti, & Shabbat, 2011 [Level IV]; Boltz et al., 2010 [Level IV]).
- *Physical design*
 - Toilets, beds, and chairs at appropriate height to promote safe transfers and function (Capezuti et al., 2008 [Level IV]).
 - Functional and accessible furniture and safe walking areas with relevant/interesting destination areas (Gulwadi & Calkins, 2008 [Level V]; Ulrich et al., 2008 [Level V]) and with distance markers (Callen et al., 2004 [Level III]).
 - Adequate lighting, nonglare flooring, door levers, and hand rails (including in the patient room) (Gulwadi & Calkins, 2008; Ulrich et al., 2008 [Level V]).
 - Large-print calendars and clocks to promote orientation (Kleinpell, 2007 [Level V]).

- Control of ambient noise levels (Gabor et al., 2003 [**Level III**])
- *Education of nursing staff, and other members of the interdisciplinary team (e.g., social work, physical therapy), regarding:*
 - The physiology, manifestations, and prevention of hospital-acquired deconditioning (Boltz, Capezuti, & Shabbat, 2011 [**Level IV**]; Gillis, MacDonald, & Macisaac, 2008 [**Level IV**]; Resnick et al., 2011 [**Level III**]; Weitzel & Robinson, 2004 [**Level V**])
 - Assessment of physical capability (Resnick et al., "Implementation," 2009 [**Level III**]; Resnick et al., 2011 [**Level III**])
 - Rehabilitative techniques and use of adaptive equipment (Weitzel & Robinson, 2004 [**Level V**]; Resnick et al., 2011 [**Level III**]; Resnick et al., "Implementation," 2009 [**Level III**])
 - Interdisciplinary collaboration (Resnick et al., 2011 [**Level III**]; Resnick et al., "Implementation," 2009 [**Level III**])
 - Engagement in decision making (Boltz, Capezuti, & Shabbat, 2011 [**Level IV**]; Boltz et al., 2010 [**Level IV**]; Jacelon, 2004 [**Level IV**])
 - Communication that motivates is associated with a function-promoting philosophy (Boltz, Capezuti, & Shabbat, 2011 [**Level IV**]; Gillis, MacDonald, & Macisaac, 2008 [**Level IV**]; Jacelon, 2004 [**Level IV**]; Weitzel & Robinson, 2004 [**Level V**])
- *Education of patients and families regarding FFC (Resnick et al., "Implementation," 2009 [**Level III**]), including the benefits of FFC, the safe use of equipment, and self-advocacy (Boltz et al., 2010 [**Level IV**]).*
- *Clinical assessment and interventions*
 - Assessment of physical function and capability (baseline, at admission, and daily) and cognition (at a minimum daily) (Boltz, Capezuti, & Shabbat, 2011 [**Level IV**]; Covinsky et al., 2003 [**Level IV**]; Fortinsky et al., 1999 [**Level IV**]; Sager et al., 1996 [**Level IV**]; Wakefield & Holman, 2007 [**Level IV**])
 - Establishing functional goals based on assessments and communication with other members of the team and input from patients (Resnick et al., "Implementation," 2009 [**Level III**]; Resnick et al., 2011 [**Level III**]; Resnick et al., "Changing," 2009 [**Level III**]; Resnick et al., 2007 [**Level III**]; Resnick & Simpson, 2003 [**Level III**])
 - Social assessment: history, roles, values, living situation, and methods of coping (Boltz, Capezuti, & Shabbat, 2011 [**Level IV**]; Boltz et al., 2010 [**Level IV**])
 - Addressing risk factors that impact goal achievement (e.g., cognitive status, anemia, nutritional status, pain, fear of falling, fatigue, medications, and drug side effects such as somnolence) by the interdisciplinary team to optimize patient participation in functional and physical activity (Boltz et al., 2011 [**Level IV**]; Resnick et al., "Implementation," 2009 [**Level III**]; Resnick et al., 2011 [**Level III**]; Resnick et al., "Changing," 2009 [**Level III**]; Resnick et al., 2007 [**Level III**]; Resnick & Simpson, 2003 [**Level III**])
 - Development of discharge plans that include carryover of functional interventions, and addressing the unique preferences and needs of the patient (Nolan & Thomas, 2008 [**Level III**])

HIGN Clinical Guideline for Assessment and management of mealtime difficulties

Group: Hartford Institute for Geriatric Nursing

Target population: Hospitalized or institutionalized older adults

Link: <http://www.guideline.gov/content.aspx?id=43930&search=functional+status>

Date: 2003 (revised 2012)

Rating Scheme for the Level of Evidence

Level I: Systematic reviews (integrative/meta-analyses/clinical practice guidelines based on systematic reviews)

Level II: Single experimental study (randomized controlled trials [RCTs])

Level III: Quasi-experimental studies

Level IV: Non-experimental studies

Level V: Care report/program evaluation/narrative literature reviews

Level VI: Opinions of respected authorities/consensus panels

Major Recommendations

Parameters of Assessment:

Assessment of Older Adult and Caregivers

- Rituals used before meals (e.g., hand washing and toilet use), dressing for dinner
- Blessings of food or grace, if appropriate
- Religious rites or prohibitions observed in preparation of food or before meal begins (e.g., Muslim, Jewish, and Seventh Day Adventist; consult with pastoral counselor, if available)
- Cultural or special cues: family history, especially rituals surrounding meals
- Preferences about end-of-life decisions regarding withdrawal or administration of food and fluid in the face of incapacity, or request of designated health proxy; ethicist or social worker may facilitate process

Assessment Instruments

- Edinburgh Feeding Evaluation in Dementia Scale (EdFED) for persons with moderate- to late-stage dementia (Watson, 1994[**Level III**]).
- Katz Index of Activities of Daily Living (ADL) for functional status (Katz et al., 1970 [**Level IV**])
- Food diary/meal portion method (Berrut et al., 2002 [**Level III**])

Nursing Interventions

Environment

- Dining or patient room: encourage older adult to eat in dining room to increase intake, personalize dining room; no treatments or other activities occurring during meals; no distractions.
- Tableware: use of standard dinnerware (e.g., china, glasses, cup and saucer, flatware, tablecloth, napkin) versus disposable tableware and bibs
- Furniture: older adult seated in stable arm chair; table-appropriate height versus eating in wheelchair or in bed
- Noise level: environmental noise from music, caregivers, and television is minimal; personal conversation between patient and caregiver is encouraged
- Music: pleasant, preferred by patient
- Light: adequate and non-glare-producing versus dark, shadowy or glaring
- Contrasting background/foreground: use contrasting background and foreground colors with minimal design to aid persons with decreased vision

- Odor: food prepared in area adjacent to or in dining area to stimulate appetite
- Adaptive equipment: available, appropriate and clean; caregivers and/or older adult knowledgeable in use; occupational therapist assists in evaluation

Caregiver/Staffing

- Provide an adequate number of well-trained staff.
- Deliver an individualized approach to meals including choice of food, tempo of assistance.
- Position of caregiver relative to elder: eye contact; seating so caregiver faces older patient in same plane.
- Cueing: caregiver cues older adult whenever possible with words or gestures.
- Self-feeding: encouragement to self-feed with multiple methods versus assisted feeding to minimize time.
- Mealtime rounds: interdisciplinary team to examine multifaceted process of meal service, environment and individual preferences.

Follow-up Monitoring

- Providers' competency to monitor eating and feeding behaviors
- Documentation of eating and feeding behaviors
- Documentation of care strategies and follow-up of alterations in nutritional status, eating and feeding behaviors
- Documentation of staffing and staff education; availability of supportive interdisciplinary team

HIGN Clinical Guideline for Assessing Cognitive Function

Group: Hartford Institute for Geriatric Nursing (HIGN)

Target population: Hospitalized Older Adults

Link: <http://www.guideline.gov/content.aspx?id=43917&search=functional+status+assessment>

Date: 2003 (Revised 2012)

Rating Scheme for the Level of Evidence

Levels of Evidence

Level I: Systematic reviews (integrative/meta-analyses/clinical practice guidelines based on systematic reviews)

Level II: Single experimental study (randomized controlled trials [RCTs])

Level III: Quasi-experimental studies

Level IV: Non-experimental studies

Level V: Care report/program evaluation/narrative literature reviews

Level VI: Opinions of respected authorities/consensus panels

Major Recommendations

Assessment of Cognitive Function

Reasons/Purposes of Assessment

- Screening: to determine the absence or presence of impairment (Foreman et al., 2003 [Level VI]).
- Monitoring: to track cognitive status over time, especially response to treatment (Foreman et al., 2003 [Level VI]).

How to Assess Cognitive Function

- Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975 [Level VI]) can be used to screen for or monitor cognitive function; however, performance on the MMSE is adversely influenced by education, age, language, and verbal ability. The MMSE also is criticized for taking too long to administer and score.
- Mini-Cog (Borson et al., 2000 [Level VI]) or Sweet 16 (Fong et al., 2011 [Level VI]) can also be used to screen and monitor cognitive function; is not adversely influenced by age, language, and education; and takes about half as much time to administer and score as the MMSE.
- Informant Questionnaire on Cognitive Decline in the Elderly (IQCDE) is useful to supplement testing with the MMSE or Mini-Cog as it is useful to determine onset, duration, and functional impact of the cognitive impairment. Information from intimate others can be obtained by using the IQCDE (Jorm, 1994 [Level VI]).
- Naturally occurring interactions: Observations and conversations during naturally occurring care interactions can be the impetus for additional screening/monitoring of cognitive function with the MMSE or Mini-Cog (Foreman et al., 2003 [Level VI]). Furthermore, observations should be standardized by using a formal observation instrument such as the Nurses' Observation Scale for Cognitive Abilities (Persoon, 2010 [Level IV]).

When to Assess Cognitive Function

- On admission to and discharge from an institutional care setting (British Geriatrics Society, 2005 [Level I]; Shekelle et al., 2001 [Level I]).

- Upon transfer from one care setting to another (Shekelle et al., 2001 [Level I]).
- During hospitalization, every 8 to 12 hours throughout hospitalization (<http://www.mc.vanderbilt.edu/icudelirium>).
- As follow-up to hospital care, within 6 weeks of discharge (Shekelle et al., 2001 [Level I]).
- Before making important health care decisions as an adjunct to determining an individual's capacity to consent (Shekelle et al., 2001 [Level I]).
- On the first visit to a new care provider (Shekelle et al., 2001 [Level I]).
- Following major changes in pharmacotherapy (Shekelle et al., 2001 [Level I]).
- With behavior that is unusual for the individual and/or inappropriate to the situation (Foreman & Vermeersch, 2004 [Level I]).

Cautions for Assessing Cognitive Function

Physical Environment (Dellasega, 1998 [Level VI])

- Comfortable ambient temperature.
- Adequate lighting (i.e., not glaring).
- Free of distractions (e.g., should be conducted in the absence of others and other activities).
- Position self to maximize individual's sensory abilities.

Interpersonal Environment (Engberg & McDowell, 1999 [Level VI])

- Prepare individual for assessment.
- Initiate assessment within nonthreatening conversation.
- Let individual set pace of assessment.
- Be emotionally nonthreatening.

Timing of Assessment (Foreman et al., 2003 [Level VI])

- Select time of assessment to reflect actual cognitive abilities of the individual.
- Avoid the following times:
 - Immediately on awakening from sleep; wait at least 30 minutes
 - Immediately before and after meals
 - Immediately before and after medical diagnostic or therapeutic procedures
 - In the presence of pain or discomfort

Follow-up Monitoring

- Provider competence in the assessment of cognitive function.
- Consistent and appropriate documentation of cognitive assessments.
- Consistent and appropriate care and follow-up in instances of impairment.
- Timely and appropriate referral for diagnostic and treatment recommendations.

NICE Clinical Guideline for Rehabilitation after critical illness

Group: National Institute for Health and Care Excellence (NICE)

Target population: Adults with rehabilitation needs as a result of a period of critical illness that required level 2 and level 3 Critical Care

Link: <http://www.guideline.gov/content.aspx?id=14343&search=functional+status>

Date: March 2009

Major Recommendations

Key Principle of Care

To ensure continuity of care, healthcare professional(s) with the appropriate competencies should coordinate the patient's rehabilitation care pathway. (Note: The healthcare professional(s) may be intensive care professional(s) or, depending on local arrangements, any appropriately trained healthcare professional(s) from a service [including specialist rehabilitation medicine services] with access to referral pathways and medical support [if not medically qualified]). Key elements of the coordination are as follows:

- Ensure the short-term and medium-term rehabilitation goals are reviewed, agreed and updated throughout the patient's rehabilitation care pathway
- Ensure the delivery of the structured and supported self-directed rehabilitation manual, when applicable
- Liaise with primary/community care for the functional reassessment at 2 to 3 months after the patient's discharge from critical care
- Ensure information, including documentation, is communicated between hospitals and to other hospital-based or community rehabilitation services and primary care services
- Give patients the contact details of the healthcare professional(s) on discharge from critical care, and again on discharge from hospital

During the Critical Care Stay

During the patient's critical care stay and as early as clinically possible, perform a short clinical assessment to determine the patient's risk of developing physical and non-physical morbidity (see table 1 in the original guideline document).

For patients at risk of physical and non-physical morbidity, perform a comprehensive clinical assessment to identify their current rehabilitation needs. This should include assessments by healthcare professionals experienced in critical care and rehabilitation.

For patients at risk, agree short-term and medium-term rehabilitation goals, based on the comprehensive clinical assessment. The patient's family and/or carer should also be involved. (Note: During the critical care stay, the patient may not gain full consciousness or may not have full capacity to give formal consent. Therefore, the involvement of the family and/or carer is important at this stage.) The comprehensive clinical assessment and the rehabilitation goals should be collated and documented in the patient's clinical records.

For patients at risk, start rehabilitation as early as clinically possible, based on the comprehensive clinical assessment and the rehabilitation goals. Rehabilitation should include:

- Measures to prevent avoidable physical and non-physical morbidity, including a review of previous and current medication
- Nutrition support, based on the recommendations in the National Institute for Health and Clinical Excellence (NICE) clinical guideline; no 32 Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition .

- An individualised, structured rehabilitation programme with frequent follow-up reviews. The details of the structured rehabilitation programme and the reviews should be collated and documented in the patient's clinical records

Give patients the following information during their critical care stay. Also give the information to their family and/or carer, unless the patient disagrees. (Note: During critical care stay, the patient may not gain full consciousness or may not have full capacity to give formal consent. Therefore, the involvement of family and/or carer is important at this stage.)

- Information about the patient's critical illness, interventions and treatments
- Information about the equipment used during the patient's critical care stay
- If applicable, information about any possible short-term and/or long-term physical and non-physical problems which may require rehabilitation

Deliver all the above information more than once during the patient's critical care stay.

Before Discharge from Critical Care

For patients who were previously identified as being at low risk, perform a short clinical assessment before their discharge from critical care to determine their risk of developing physical and non-physical morbidity (see table 1 in the original guideline document).

For patients at risk, and patients who started the individualised, structured rehabilitation programme in critical care, perform a comprehensive clinical reassessment to identify their current rehabilitation needs. The comprehensive reassessment should pay particular attention to:

- Physical, sensory and communication problems (see table 2 in the original guideline document)
- Underlying factors, such as pre-existing psychological or psychiatric distress
- Symptoms that have developed during the critical care stay, such as delusions, intrusive memories, anxiety, panic episodes, nightmares, flashback episodes or depression

For patients who were previously identified as being at risk during critical care, the outcomes of the comprehensive reassessment should inform the individualised, structured rehabilitation programme. For patients at risk, agree or review and update the rehabilitation goals, based on the comprehensive reassessment. The family and/or carer should also be involved, unless the patient disagrees. Ensure that the transfer of patients and the formal structured handover of their care are in line with 'Acutely ill patients in hospital' (NICE clinical guideline 50). This should include the formal handover of the individualised, structured rehabilitation programme.

Give patients the following information before, or as soon as possible after, their discharge from critical care. Also give the information to their family and/or carer, unless the patient disagrees.

- Information about the rehabilitation care pathway.
- Information about the differences between critical care and ward-based care. This should include information about the differences in the environment, and staffing and monitoring levels.
- Information about the transfer of clinical responsibility to a different medical team (this includes information about the formal structured handover of care recommended in the NGC summary of the NICE clinical guideline; no 50 Acutely ill patients in hospital: recognition of and response to acute illness in adults in hospital [\[7\]](#)).
- If applicable, emphasise the information about possible short-term and/or long-term physical and non-physical problems that may require rehabilitation.

- If applicable, information about sleeping problems, nightmares and hallucinations and the readjustment to ward-based care.

Before Discharge to Home or Community Care

Before discharging patients who were receiving the individualised structured rehabilitation programme during ward-based care:

- Perform a functional assessment which should include the following (also see table 2 in the original guideline document for possible examples):

Physical Dimensions

- Physical problems
- Sensory problems
- Communication problems
- Social care or equipment needs

Non-physical Dimensions

- Anxiety
- Depression
- Post-traumatic stress-related symptoms
- Behavioural and cognitive problems
- Psychosocial problems
- Assess the impact of the outcomes from the functional assessment on the patient's activities of daily living and participation
- Based on the functional assessment, review, update and agree the rehabilitation goals with the patient. The family and/or carer should be involved if the patient agrees.

If continuing rehabilitation needs are identified from the functional assessment, ensure that before the patient is discharged:

- Discharge arrangements, including appropriate referrals for the necessary ongoing care, are in place before completing the discharge
- All discharge documents are completed and forwarded to the appropriate post-discharge services and the patient
- The patient, and/or the family and/or carer as appropriate, is aware of the discharge arrangements and understands them

Give patients the following information before their discharge to home or community care. Also give the information to their family and/or carer, if the patient agrees.

- Information about their physical recovery, based on the goals set during ward-based care if applicable
- If applicable, information about diet and any other continuing treatments
- Information about how to manage activities of daily living including self-care and re-engaging with everyday life
- If applicable, information about driving, returning to work, housing and benefits
- Information about local statutory and non-statutory support services, such as support groups
- General guidance, especially for the family and/or carer, on what to expect and how to support the patient at home. This should take into account both the patient's needs and the family's/carer's needs
- Give the patient their own copy of the critical care discharge summary

2 to 3 Months after Discharge from Critical Care

Review patients with rehabilitation needs 2 to 3 months after their discharge from critical care. Carry out a functional reassessment of their health and social care needs, using the dimensions in the above recommendation. If appropriate, also enquire about sexual dysfunction.

The functional reassessment should be face to face in the community or in hospital, performed by an appropriately-skilled healthcare professional(s) who is familiar with the patient's critical care problems and rehabilitation care pathway.

Based on the Functional Reassessment

- Refer the patient to the appropriate rehabilitation or specialist services if:
 - The patient appears to be recovering at a slower rate than anticipated, according to their rehabilitation goals.
 - The patient has developed unanticipated physical and/or non-physical morbidity that was not previously identified.
- Give support if the patient is not recovering as quickly as they anticipated.
- If anxiety or depression is suspected, follow the stepped care models recommended in 'Anxiety' (NICE clinical guideline 22) and 'Depression' (NICE clinical guideline 23).
- If PTSD is suspected or the patient has significant symptoms of PTS, refer to the National Institute for Health and Clinical Excellence (NICE) clinical guideline; no 26 'Post-traumatic stress disorder. The management of PTSD in adults and children in primary and secondary care.'

HPB Clinical Guideline for Functional screening for older adults in the community

Group: Health Promotion Board (HPB), Singapore; Singapore Ministry of Health

Target population: Older community-dwelling adults living in Singapore

Link:

<http://www.guideline.gov/content.aspx?id=39343&search=functional+assessment+and+functional+assessment>

Date: June 2010

Rating Scheme for the Strength of the Recommendations and Level of Evidence

Grades of Recommendation

Grade A: At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

Grade B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+

Grade C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++

Grade D: Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+

Grade GPP (good practice points): Recommended best practice based on the clinical experience of the guideline development group.

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g., case reports, case series

4: Expert opinion

Major Recommendations

Physical Function

Screening

C - Community-dwelling older adults should be screened for functional disability. (**Grade C, Level 2+**)

Possible Tools

C - The Vulnerable Elders Survey-13 (VES-13) and the Short Physical Performance Battery (SPPB) can be used to screen for functional disability in older adults. (**Grade C, Level 2+**)

Post-Screening Follow-up

D - Older adults who score ≥ 3 on the VES-13 or ≤ 6 on the SPPB tools can be considered for referral to a primary care physician. **(Grade D, Level 4)**

Vision

Screening

GPP - Community-dwelling older adults should be screened for visual impairment. **(GPP)**

Specific Tool

B - A visual acuity chart (e.g., Snellen chart) is recommended for identifying the presence of visual impairment. **(Grade B, Level 2++)**

Post-Screening Follow-up

GPP - Older adults with visual acuity 6/12 or better (acceptable/normal visual acuity) should be screened every 1-2 years. **(GPP)**

GPP - Individuals with visual acuity worse than 6/12 (abnormal visual acuity) without pinhole on initial screening should have visual acuity testing repeated with pinhole.

Individuals with pinhole visual acuity of 6/12 or better are likely to have refractive error and should be referred to an optometrist based in an optical outlet.

Individuals with pinhole visual acuity worse than 6/12 may have eye conditions other than refractive error and should be referred to an ophthalmologist.

(GPP)

See algorithm in Section 3.5 of the original guideline document.

Hearing

Screening

B - Community-dwelling older adults should be screened for hearing impairment. **(Grade B, Level 1+)**

Specific Tool

D - The Single Global Screening Question: 'Do you or your family think that you may have hearing loss?' is recommended as a first screening tool for hearing impairment, although mild hearing impairment might still be missed. **(Grade D, Level 2+)**

C - The Hearing Handicap Inventory for the Elderly-Screening (HHIE-S) is recommended as a screening tool for hearing impairment. **(Grade C, Level 2+)**

B - The audioscope is recommended as a screening tool for hearing impairment. **(Grade B, Level 2++)**

GPP -The algorithm in Section 4.5 of the original guideline document is recommended for the screening of hearing impairment in older adults. **(GPP)**

Post-Screening Follow-up

GPP - Currently in Singapore, individuals that fail any of the three tests (Single Global Screening Question, HHIE-S, & audioscope test) should be referred to an audiologist and/or otolaryngologist. **(GPP)**

GPP - For older adults that have been screened for hearing impairment and found to have normal hearing, screening for hearing impairment should be repeated yearly. **(GPP)**

Oral Health

Screening

D - All individuals should be screened on their level of oral cleanliness, number and condition of teeth, health of oral tissues, characteristics of saliva, condition of prosthesis, as well as the signs and symptoms of dental pain. **(Grade D, Level 3)**

Specific Tool

D - Individuals should be screened using the Oral Health Assessment Tool (OHAT). **(Grade D, Level 3)**

Post-Screening Follow-up

D - It is recommended that:

- Individuals with only poor oral hygiene should be provided with advice and skills to improve oral self-maintenance.

- Individuals with oral pain, dry mouth, poor dentition status, poor periodontal health; in need of oral prosthesis; or have existing prosthesis in need of repair/relining should be referred to a dentist.

(Grade D, Level 3)

See algorithm in Section 5.5 in the original guideline document.

Continence

Screening

D - Community-dwelling older adults should be screened for urinary incontinence. **(Grade D, Level 3)**

Specific Tool

D - Individuals should be screened for urinary incontinence with the International Consultation on Incontinence Questionnaire Urinary Incontinence – Short Form (ICIQ-UI SF). **(Grade D, Level 3)**

Post-Screening Follow-up

GPP - Older adults with an ICIQ score of 1 or greater are recommended to visit a primary care physician for further evaluation and follow-up consultation. **(GPP)**

See algorithm in Section 6.5 of the original guideline document.

Mood

Screening

GPP - Community-dwelling older adults should be screened for depression. **(GPP)**

Specific Tool

B - It is recommended that the 15-item Geriatric Depression Scale (GDS-15) be used to screen for depression among older adults. **(Grade B, Level 2++)**

Post-Screening Follow-up

C - Individuals who score 5 or more points on the GDS-15 must be referred to primary care doctors for further assessment and treatment. Primary care doctors can refer the more complicated patients to mental health professionals for treatment as necessary (see algorithm in Section 7.6 of the original guideline document). **(Grade C, Level 2++)**

Cognition

C - Currently, community screening or routine screening in the primary care setting for dementia in asymptomatic older persons **is not recommended**. **(Grade C, Level 2+)**

RPA Clinical Guideline recommendations and their rationales for the treatment of adult patients

Group: Renal Physicians Association (RPA)

Target population: Adult patients with acute kidney injury, stage 4 or 5 chronic kidney disease, or end-stage renal disease

Link: <http://www.guideline.gov/content.aspx?id=24176&search=functional+status>

Date: Jan 2000 (revised October 2010)

Major Recommendations

Informing Patients

Recommendation No 2: Fully Inform AKI, Stage 4 and 5 CKD, and ESRD Patients about Their Diagnosis, Prognosis, and All Treatment Options

In the setting of critical illness many patients with CKD will require urgent dialysis and the vast majority of patients with AKI will have multiple medical problems, in addition to kidney failure. The concept of shared decision making necessitates a multidisciplinary approach including nephrologists, intensivists, and others as appropriate and decisions about acute renal replacement therapy should be made in the context of other life-sustaining treatments. For example, a decision to withhold dialysis in a patient agreeing to and receiving multiple other forms of life sustaining therapy could represent discordant treatment in the same way that offering dialysis to a patient who has decided to forgo other forms of life-sustaining therapy might be inappropriate. Intensive care physicians need to be included in shared decision making for kidney patients in the intensive care unit (ICU).

For ESRD patients, these options in shared decision-making include: 1) available dialysis modalities and kidney transplantation if applicable; 2) not starting dialysis and continuing medical management; 3) a time limited trial of dialysis, and 4) stopping dialysis and receiving end-of-life care. Choices among options should be made by patients or, if patients lack decision-making capacity, their designated legal agents. Their decisions should be informed and voluntary. The renal care team, in conjunction with the primary care physician, should insure that the patient or legal agent understands the benefits and burdens of dialysis and the consequences of not starting or stopping dialysis. Research studies have identified a population of chronic kidney disease patients for whom the prognosis is particularly poor. This population has been found to include patients with two or more of the following characteristics: 1) elderly (defined by research studies identifying poor outcomes in patients who are age 75 years and older); 2) patients with high comorbidity scores (e.g., modified Charlson Comorbidity Index score of 8 or greater); 3) marked functional impairment (e.g., Karnofsky Performance Status Scale score of less than 40); and 4) severe chronic malnutrition (e.g., serum albumin level less than 2.5 g/dL using the bromocresol green method). Patients in this population should be informed that dialysis may not confer a survival advantage or improve functional status over medical management without dialysis and that dialysis entails significant burdens that may detract from their quality of life.

Suggested Steps for Implementing Recommendation No 2:

- Identify provider(s) who will coordinate communication with the patient or legal agent and family (e.g., nephrologist in conjunction with the primary care provider for ESRD patients or intensivists for AKI).
- Assess patient decision-making capacity and whether it is diminished by major depression, encephalopathy, or other disorder (see Tool 4 in Section 9: Toolkit for helpful instruments in the full version of the current guideline). Obtain psychiatric and/or neurological consultation as appropriate, and institute treatment for conditions impairing decision-making capacity.
- Communicate diagnosis to patient (or legal agent) and family (if the patient agrees).

- Discuss prognosis based upon patient's medical condition, comorbidities, functional status, and age (see Tools 6-1 to 6-3 in Section 9: Toolkit for tools for assessing functional status and quality of life, and estimating prognosis in the full version of the current guideline).
- Identify the patient's wishes.
- Communicate options, taking advantage of educational resources, such as other patients or videotapes and brochures.
- If the patient wants to forgo dialysis, determine why. •Are the patient's perceptions about dialysis accurate? Does the patient know what to expect if dialysis is not started or is discontinued?
- Does the patient really mean what he/she says or is the decision to refuse or stop dialysis made to get attention, help, or control?
- Are there changes that might improve quality of life and would the patient be willing to start or continue dialysis while the factors responsible for the patient's request are addressed?
- Are there persons (e.g., social worker, chaplain) with whom the patient would be willing to discuss the decision?
- Reach decision based on medical indications and patient's preferences.
- Encourage patient to discuss end-of-life issues with others such as family, friends, or spiritual advisors (see Tool 5-1 in Section 9 in the full version of the current guideline: Toolkit for helpful questions to use).
- Refer for palliative care and hospice as appropriate.

National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines

Group: NKF KDOQI

Target population: Patients with Chronic Kidney Disease

Link: http://www.kidney.org/professionals/KDOQI/guidelines_ckd/toc.htm

Date: 2002

Rating Scheme for the Strength of the Recommendations and Level of Evidence

Grading Rationale Statements:

S: Analysis of individual patient data from a single large, generalizable study of high methodological quality (for example, NHANES III)

C: Compilation of original articles (evidence tables)

R: Review of reviews and selected original articles

O: Opinion

Major Recommendations

GUIDELINE 12. ASSOCIATION OF LEVEL OF GFR WITH INDICES OF FUNCTIONING AND WELL-BEING

Impairments in domains of functioning and well-being develop during the course of chronic kidney disease and are associated with adverse outcomes. Impaired functioning and well-being may be related to sociodemographic factors, conditions causing chronic kidney disease, complications of kidney disease, or possibly directly due to reduced GFR.

- Patients with GFR ≤ 60 mL/min/1.73 m² should undergo regular assessment for impairment of functioning and well-being:
- To establish a baseline and monitor changes in functioning and well-being over time
- To assess the effect of interventions on functioning and well-being.

CLINICAL APPLICATIONS

The conferees at the Institute of Medicine (IOM) Workshop “Assessing Health and Quality of Life Outcomes in Dialysis” recommended that ESRD providers:

Assess functioning and well-being in kidney disease using standardized survey instruments that are valid, reliable, responsive to changes, easily interpretable, and easy to use, such as the Dartmouth COOP Charts, the Duke Health Profile/Duke Severity of Illness (DUKE/DUSOI), Medical Outcomes Study 36-Item Short Form (SF-36), or the Kidney Disease Quality of Life (KDQOL).

- Assess patient functioning and well-being early in chronic kidney disease to establish a baseline, to maintain or improve health status, and to manage the disease continuum by linking clinical and health outcomes with functional status outcomes. 454 Data reported in the reviewed studies suggest that decreased kidney function affects patients’ functioning and well-being through several dimensions. Deficits in functioning are reported by patients even at early stages of chronic kidney disease, and persist even after transplantation. The implications of these findings are:
- Clinicians should assess functional status and well-being as soon as possible after referral in order to obtain baseline data and enable early intervention to improve functioning and well-being.
- Clinicians should regularly reassess functioning and well-being to ascertain the patient’s current status and the effectiveness of interventions to improve functioning and well-being. Reassessment is needed when a patient reports increased frequency or severity of symptoms, has a new complication of kidney disease, has an access for dialysis placed, starts dialysis,

changes modality, or participates in a clinical or rehabilitation intervention (eg, counseling, peer support, education, physical therapy or independent exercise, or vocational rehabilitation). These recommendations are based on the opinions expressed by the authors of most of the studies reviewed for this guideline, as well as those of recognized experts in functioning and health status outcomes measurement who attended the IOM Workshop.

Strength of Evidence

Indices of functioning and well-being are impaired in chronic kidney disease

(R). Dialysis patients report significantly more bodily pain, lower vitality, poorer general health, greater physical, mental, and social dysfunction, and greater limitations in their ability to work and participate in activities due to their health and emotions than the US reference norm. At least 25% are depressed.⁴⁵⁵ Dialysis patients' exercise capacity is significantly worse than that of healthy controls.⁴⁵⁶ Kidney failure negatively affects sense of control and health outlook in those on dialysis.⁴⁵⁷ About 39% of those who worked full or part-time 6 months before dialysis do not continue working when they start dialysis.⁴ Elderly people on dialysis engage in few previously enjoyed activities outside their homes and many leave home only for dialysis because of weakness.⁴⁵⁸

Impairment in indices of functioning and well-being are associated with worse outcomes in chronic kidney disease

(R). Impaired functioning and wellbeing in dialysis patients is linked to increased risk of death and hospitalization while improvement in scores has been associated with better outcomes. Patients with SF-36 Physical Component Summary (PCS) scores ≤ 34.6 had a 2.03 relative risk of dying and a 1.67 relative risk of being hospitalized. Each 5-point improvement in PCS scores was associated with 10% longer survival and 6% fewer hospital days. On the SF-36, a Mental Health scale score ≤ 52 and a Mental Component Summary (MCS) score ≤ 42 indicate depression. Each 5-point improvement in the MCS score is associated with 2% fewer hospital days.⁴⁵⁵

Impairment in functioning and well-being are associated with sociodemographic characteristics

(R). Low income and low education were associated with greater impairments in functioning and well-being in patients with chronic kidney disease. ⁴⁵⁹

Impairment in functioning and well-being may be due to conditions that cause chronic kidney disease (such as diabetes or hypertension) or complications of decreased GFR (such as anemia, malnutrition, bone disease, or neuropathy)

(R). Hypertension, diabetes with angina, prior cardiac infarction,⁴⁶⁰ osteoporosis, bone fractures,⁴⁶¹ and malnutrition⁴⁶² have been shown to impair functioning and wellbeing in those with no known kidney disease. Among veterans with diabetes, neuropathy and kidney disease have been associated with the greatest decrease in functioning and well-being.⁴⁶³ Anemia has been linked to poor functioning and well-being in patients with severely decreased GFR and dialysis patients, and improving anemia with erythropoietin has been linked to improvement in functioning and well-being.^{284,464–468}

Indices of functioning and well-being are related to the level of GFR; below a GFR of approximately 60 mL/min/1.73 m², there is a higher prevalence of impairments in indices of functioning and well-being

(S, C). Data from cross-sectional studies and baseline data from longitudinal studies were reviewed to assess the relationship between level of kidney function and level of functioning and well-being. Populations studied include those with decreased kidney function, including those with functioning transplants, and dialysis patients when compared with healthy subjects or kidney transplant recipients. While much of the data on functioning and well-being related to outcomes have been obtained in

dialysis patients, there is convincing evidence that abnormalities in functioning and well-being begin earlier in chronic kidney disease and may well be related to declining GFR.

Symptoms (Table 103 and Fig 44). Reduced kidney function is associated with increasing symptoms such as tiring easily, weakness, low energy, cramps, bruising, bad tasting mouth, hiccoughs, and poor odor perception. This is true in patients with native kidney disease and those with kidney transplants. Diabetic dialysis and transplant patients are more likely to report poor health than dialysis or transplant patients who do not have diabetes.

Physical Functioning (Table 104 and Figs 45 and 46). Decreased GFR in NHANES III subjects is associated with impaired walking and lifting ability. In transplant recipients, reduced kidney function is also associated with poorer physical function scores. In one study of patients with decreased GFR, impairment in physical function was not significantly related to the level of kidney function, but physical impairment was 8 times worse than in the general population. Dialysis patients report greater physical dysfunction than transplant recipients and diabetic dialysis and transplant patients are more likely to report physical dysfunction than those patients who do not have diabetes.

Depression (Table 105). Reduced kidney function is associated with poorer psychosocial functioning, higher anxiety, higher distress, decreased sense of well-being, higher depression, and negative health perception. Depressed patients are more likely to report poor life satisfaction, irrespective of kidney function. Dialysis patients report significantly lower “happiness with personal life” and lower psychosocial functioning than transplant recipients. In elderly Mexican Americans, kidney disease has been found to be predictive of depressive symptoms.

Employment and Usual Activities (Table 106). Reduced kidney function is associated with lower employment. In those with chronic kidney disease and GFR \leq 50, the presence of physical dysfunction is significantly related to unemployment, but the association to kidney function is not significant since physical dysfunction is not uniformly present. Full-time employment is higher for those with decreased GFR (mean serum creatinine 5.4 mg/dL, 69%) compared with those with kidney failure (mean serum creatinine 13.7 mg/dL, 12%). More dialysis patients report their health limits work and other activities than those with functioning transplants. Dialysis and transplant patients with diabetes are more likely to report difficulty working than dialysis and transplant patients without diabetes.

Social Functioning (Table 107). Reduced kidney function is associated with reduced social activity, social functioning, and social interaction. Dialysis patients report fewer neighborhood acquaintances, social contacts, and worse social well-being than healthy individuals while transplant recipients report higher social function and social interaction than those on dialysis. Diabetics on dialysis or with transplants are more likely to report problems with social interaction than nondiabetic patients. Level of perceived social support in chronic kidney disease is not associated with the level of kidney function.

*****Extra Detail Below*****

BACKGROUND

When there is no cure for a chronic illness, an essential healthcare goal must be to maximize quality of life. The purpose of this guideline is to identify stages and complications of kidney disease that place adult patients at greater risk for reduced quality of life. This guideline is not intended to cover all the quality of life concerns that apply to children and adolescents, nor is it intended to recommend interventions to improve quality of life in any age group. For the purpose of this guideline, concepts that embody pertinent components of quality of life will be referred to as “functioning and wellbeing.” Recent studies show that the functioning and well-being of individuals with chronic kidney disease is related to such factors as: late referral and inadequate predialysis care⁸⁰; symptoms; effects of illness on physical, psychological, and social functioning;

and satisfaction with health and care.⁴⁵² Complications of chronic kidney disease, such as anemia, malnutrition, bone disease, neuropathy, and comorbid conditions, such as diabetes and cardiovascular disease, can negatively affect functioning and well-being. To improve functioning and well-being, patients must be referred sooner and complications and comorbid conditions must be managed appropriately.

This guideline describes the association between the level of kidney function and domains of functioning and well-being in patients with chronic kidney disease. One must analyze the full continuum of stages of chronic kidney disease to understand the risks for compromised functioning and well-being. Armed with this knowledge, clinicians can more quickly identify stages of chronic kidney disease at which deficits are likely to

occur and develop strategies to treat higher risk patients and ameliorate or eliminate deficits before they become severe or irreversible.

RATIONALE

Definitions

Health status outcomes experts recommend defining “quality of life” to include variables that health professionals can identify, quantify, and modify: (1) health status (signs and symptoms, lab values, death); (2) functional status (physical, mental, social, and role functioning), and (3) well-being (energy/fatigue, pain, health perceptions, and satisfaction).

^{453,454} Self-report is preferable to staff report since outcomes are dependent on the lived experience and expectations of the individual patient.

Difficulties in measuring this poorly understood concept have led researchers in the articles reviewed to study several variables using different methods and instruments (Table 102). Use of different instruments has impeded comparing findings, interpreting results, and drawing conclusions.

Strength of Evidence

Indices of functioning and well-being are impaired in chronic kidney disease

(R). Dialysis patients report significantly more bodily pain, lower vitality, poorer general health, greater physical, mental, and social dysfunction, and greater limitations in their ability to work and participate in activities due to their health and emotions than the US reference norm. At least 25% are depressed.⁴⁵⁵ Dialysis patients’ exercise capacity is significantly worse than that of healthy controls.⁴⁵⁶ Kidney failure negatively affects sense of control and health outlook in those on dialysis.⁴⁵⁷ About 39% of those who worked full or part-time 6 months before dialysis do not continue working when they start dialysis.⁴ Elderly people on dialysis engage in few previously enjoyed activities outside their homes and many leave home only for dialysis because of weakness.⁴⁵⁸

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worse outcomes in chronic kidney disease (R). Impaired functioning and wellbeing in dialysis patients is linked to increased risk of death and hospitalization while improvement in scores has been associated with better outcomes. Patients with SF-36 Physical Component Summary (PCS) scores ≥ 34.6 had a 2.03 relative risk of dying and a 1.67 relative risk of being hospitalized. Each 5-point improvement in PCS scores was associated with 10% longer survival and 6% fewer hospital days. On the SF-36, a Mental Health scale score ≥ 52 and a Mental Component Summary (MCS) score ≥ 42 indicate depression. Each 5-point improvement in the MCS score is associated with 2% fewer hospital days.⁴⁵⁵

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Impairment in functioning and well-being may be due to conditions that cause chronic kidney disease (such as diabetes or hypertension) or complications of decreased GFR (such as anemia, malnutrition, bone disease, or neuropathy)

(R). Hypertension, diabetes with angina, prior cardiac infarction,⁴⁶⁰ osteoporosis, bone fractures,⁴⁶¹ and malnutrition⁴⁶² have been shown to impair functioning and wellbeing in those with no known kidney disease. Among veterans with diabetes, neuropathy and kidney disease have been associated with the greatest decrease in functioning and well-being.⁴⁶³

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Indices of functioning and well-being are related to the level of GFR; below a GFR of approximately 60 mL/min/1.73 m², there is a higher prevalence of impairments in indices of functioning and well-being (S, C). Data from cross-sectional studies and baseline data from longitudinal studies were reviewed to assess the relationship between level of kidney function and level of functioning and well-being.

Populations studied include those with decreased kidney function, including those with functioning transplants, and dialysis patients when compared with healthy subjects or kidney transplant recipients. While much of the data on functioning and well-being related to outcomes have been obtained in dialysis patients, there is convincing evidence that abnormalities in functioning and well-being begin earlier in chronic kidney disease and may well be related to declining GFR.

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Social Functioning (Table 107). Reduced kidney function is associated with reduced social activity, social functioning, and social interaction. Dialysis patients report fewer neighborhood acquaintances, social contacts, and worse social well-being than healthy individuals while transplant recipients report higher social function and social

interaction than those on dialysis. Diabetics on dialysis or with transplants are more likely to report problems with social interaction than nondiabetic patients. Level of perceived social support in chronic kidney disease is not associated with the level of kidney function.

LIMITATIONS AND EXCEPTIONS

Most study samples were not randomly selected. Medication usage was not reported even if medications (eg, anti-depressants) could affect outcomes. Seven of 12 studies did not provide full information on patient demographics. Three studies reported differences between groups of very unequal sizes and one reported percentages but did not report whether observed differences were statistically significant.

Historically, there has been no "gold standard" definition for quality of life or functioning and well-being. Researchers have studied multiple variables using standardized and non-standardized instruments. Thus, results are not comparable to one another.⁴⁷⁹ With lack of instrument comparability, findings appear to be conflicting. Many studies have examined the relationships between functioning and well-being and treatment modalities after the onset of kidney failure. Few studies of persons with decreased GFR have examined the relationship between level of GFR and functioning and well-being. Three of the studies of individuals with decreased GFR had such severely restrictive inclusion criteria for level of kidney function that functioning and well-being deficits were already present. Of the 12 studies reported, 3 reported no measure of kidney function and 2 reported only serum creatinine, a less reliable measure of kidney function than GFR or creatinine clearance. Most of the studies reported only mean values for kidney function. Only the MDRD Study and NHANES III examined functioning and well-being at a wide range of

levels of kidney function. Precise statements about how early deficits in domains of functioning and well-being occur as kidney function deteriorates require this essential data. Finally, since anemia has been shown to limit functioning and well-being, inadequate anemia management in studies conducted prior to the widespread use of erythropoietin could have affected outcomes. Therefore, recent functioning and well-being outcomes may not be comparable to outcomes reported in studies prior to 1989 even if the same instruments were used.

CLINICAL APPLICATIONS

The conferees at the Institute of Medicine (IOM) Workshop “Assessing Health and Quality of Life Outcomes in Dialysis” recommended that ESRD providers:

Assess functioning and well-being in kidney disease using standardized survey instruments that are valid, reliable, responsive to changes, easily interpretable, and easy to use, such as the Dartmouth COOP Charts, the Duke Health Profile/Duke Severity of Illness (DUKE/DUSOI), Medical Outcomes Study 36-Item Short Form (SF-36), or the Kidney Disease Quality of Life (KDQOL).

- Assess patient functioning and well-being early in chronic kidney disease to establish a baseline, to maintain or improve health status, and to manage the disease continuum by linking clinical and health outcomes with functional status outcomes. ⁴⁵⁴Data reported in the reviewed studies suggest that decreased kidney function affects patients' functioning and well-being through several dimensions. Deficits in functioning are reported by patients even at early stages of chronic kidney disease, and persist even after transplantation. The implications of these findings are:
- Clinicians should assess functional status and well-being as soon as possible after referral in order to obtain baseline data and enable early intervention to improve functioning and well-being.
- Clinicians should regularly reassess functioning and well-being to ascertain the patient's current status and the effectiveness of interventions to improve functioning and well-being. Reassessment is needed when a patient reports increased frequency or severity of symptoms, has a new complication of kidney disease, has an access for dialysis placed, starts dialysis, changes modality, or participates in a clinical or rehabilitation intervention (eg, counseling, peer support, education, physical therapy or independent exercise, or vocational rehabilitation). These recommendations are based on the opinions expressed by the authors of most of the studies reviewed for this guideline, as well as those of recognized experts in functioning and health status outcomes measurement who attended the IOM Workshop.

IMPLEMENTATION ISSUES

Researchers may use any of a wide array of instruments to measure functioning and wellbeing throughout the course of chronic kidney disease. However, clinicians want to know what instrument to use, when to use it, and who should administer, score, and analyze the data. In general, it is practical for clinicians to use only a few instruments and to gain experience with them. Based on the literature reviewed for this guideline, it appears that any clinician treating patients with decreased GFR can administer the Dartmouth COOP Charts, DUKE Health Profiles, Kidney Disease Quality of Life, or SF-36 that have been used with dialysis and transplant patients (Table 108). In the clinical setting ease of use is essential. These surveys are recommended because each has an instructional manual and patients can complete them independently or with limited assistance. To assess specific limitations in functioning and well-being, clinicians can supplement these general instruments with more specific instruments including performance-based tests of physical functioning.

RESEARCH RECOMMENDATIONS

Research in dialysis patients has shown that functioning and well-being pre-treatment may predict post-treatment outcomes. Therefore, large-scale longitudinal studies are needed to evaluate the relationship between GFR and all domains of functional status and well-being throughout the course of progression of kidney disease. More research should be undertaken using the recommended standardized instruments and their outcomes compared. Whenever specific medications could affect outcomes, usage should

be assessed. Because conditions such as anemia, bone disease, cardiovascular, disease, and diabetes can affect functioning and well-being, researchers need to study whether appropriate management of these conditions improves functioning and well-being. Finally, researchers need to examine the effectiveness of rehabilitation interventions in earlier stages of chronic kidney disease. Doing so could provide further scientific evidence for the relationship of kidney function and treatment on patients' risk of dysfunction, hospitalization, and death and increase understanding of what interventions improve functioning and well-being and reduce the burden of chronic kidney disease on the patient, his or her family, and society.

ICSI Clinical Guideline for the Assessment and Management of Chronic Pain

Group: Institute for Clinical Systems Improvement (ICSI)

Target population: Physiologically mature adolescents (between 16 and 18 years) and adults with chronic pain

Link: <http://www.guideline.gov/content.aspx?id=47646>

Date: 2005 (revised 2011)

Rating Scheme for the Level of Evidence

Evidence Definitions:

High Quality Evidence = Further research is very unlikely to change confidence in the estimate of effect.

Moderate Quality Evidence = Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

Low Quality Evidence = Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate or any estimate of effect is very uncertain.

Major Recommendations

Clinical Highlights

- Chronic pain assessment should include determining the mechanisms of pain through documentation of pain location, intensity, quality and onset/duration; functional ability and goals; and psychological/social factors such as depression or substance abuse. (*Annotations #2, 3, 12; Aim #2*)
- The goal of treatment is an emphasis on improving function through the development of long-term self-management skills including fitness and a healthy lifestyle in the face of pain that may persist. (*Annotation #14, Aim #1*)
- A patient-centered, multifactorial, comprehensive care plan is necessary, one that includes addressing biopsychosocial factors. Addressing spiritual and cultural issues is also important. It is important to have a multidisciplinary team approach coordinated by the primary care physician to lead a team including specialty areas of psychology and physical rehabilitation. (*Annotation #14, Aim #3*)
- Level I treatment approaches should be implemented as first steps toward rehabilitation before Level II treatments are considered. (*Annotation #14; Aim #3*)

Critical First Step: Assessment

- All patients should have an adequate pain assessment that includes documentation of pain location, intensity, quality, onset/duration/variations/rhythms, manner of expressing pain, pain relief, what makes it worse, effects of pain, and a pain plan. The plan should include pain assessment tools that are appropriate for the individual, with self-report being the primary source, which includes the facilitation of regular reassessment and follow-up according to criteria developed by the individual organization.
- A general history and physical should be completed in assessing chronic pain.
- It is essential also to elicit any history of depression or other psychopathology that may affect the perception of pain [High Quality Evidence], [Low Quality Evidence]. Past or current physical,

sexual, or emotional abuse is also an important factor. A history of chemical dependency is of interest in this patient population.

- Chronic pain frequently involves the musculoskeletal system and the nervous system, especially the spine and its contents. These areas should be examined more carefully and with attention to possible generators of pain relative to the patient's history.

Functional Assessment

Many patients with chronic pain have significant losses in ability to perform normal life activities. Baseline functional ability assessment can provide objectively verifiable information about a patient's quality of life and ability to participate in normal life activities. This information may then be used for:

- Identifying significant areas of impairment or disability
- Establishing specific functional outcome goals within a care plan
- Measuring the effectiveness of the care plan or treatment interventions

Standardized assessment tools are available. Personalized goal setting, such as regaining ability to perform a specific job task, hobby, or family activity, may also be used.

Pain Assessment Tools

Patient self-report is the "most reliable indicator of the existence and intensity of pain" (National Institutes of Health) and is a key component of chronic pain assessment. Tools to assess chronic pain should:

- Be appropriate to the person regardless of age, race, creed, socioeconomic status and psychological or emotional background
- Include a multidimensional scale since chronic pain affects a person's entire being [*Low Quality Evidence*]
- Address location, quality, sensory characteristics, intensity, duration, aggravating and alleviating factors, variability, and predictability
- Be used early in the process of patient evaluation

Refer to the original guideline document for more information on the following topics: multidimensional assessment tools, single-dimensional assessment tools, patients with barriers to communications that can affect assessment, and a general approach to use of pain assessment tools in chronic pain.

Other Assessment Recommendations:

- Tools to assess chronic pain should be appropriate to the person, include a multidimensional scale and be used early in the process of patient evaluation.
- Identification and management of comorbid psychological disorders will facilitate appropriate biopsychosocial care.
- A comprehensive pain assessment begins with a determination of the biological type of pain, followed by a listing of contributing factors and barriers to treatment.

Functional Assessment Tools

A variety of assessment tools has been used in the medical literature for measuring, estimating, or describing aspects of a patient's functional ability. These tools often also include measures of pain perception and psychological status as well as function.

- Palliative Performance Scale (Karnofsky Scale) (see the NGC summary of the ICSI guideline [Palliative Care](#))
- Oswestry Low Back Disability Index (see the NGC summary of the ICSI guideline [Adult Acute and Subacute Low Back Pain](#))
- 36-item Short Form Health Survey (SF-36)
- U.S. Department of Labor Physical Demand Table
- American Pain Foundation Scale (adapted from Oken, M.M.)

These tools all have limitations, including difficulties with administration and scoring, disease- or condition-specific design or failure to provide clinically useful information, which have probably contributed to a lack of widespread clinical use.

See Appendix C in the original guideline document for The Physical Functional Ability Questionnaire (FAQ5).

Psychological Assessment

Determine possible psychiatric contribution to clinical presentation.

Assessment questions to ask the patient:

- Are you depressed or anxious?
- Are you under any psychiatric care?
- Do you have a history of substance abuse?
- Do you have a history of verbal, physical, or sexual abuse?

Refer to the original guideline document for additional information on the following topics:

- Role of psychological assessment including depression, anxiety, substance abuse and dependence, CAGE questionnaire, sleep disorders, personality disorders, and history of abuse
- Coping patterns and resources
- Spirituality
- Work and disability issues
- Contributing factors and barriers to treatment

Physical Rehabilitation with Functional Goals

Exercise therapy is commonly recommended and used in managing patients with chronic pain. In one study, sixty-one randomized controlled trials involving 6,390 participants were assessed. The authors concluded that exercise therapy is effective in reducing pain and functional limitations in the treatment of chronic low back pain. There were limitations in the quality of the studies, and improvements were small but significant over other conservative treatment options. There was also some evidence of the effectiveness of a graded exercise program in subacute low back pain primarily in reducing work absenteeism [*Meta-analysis*].

Clinical guidelines for managing patients with low back pain are available from at least 11 countries. Four countries included advice for chronic pain, and all guidelines recommend exercise therapy as useful. The American Pain Society published an evidence-based clinical practice guideline recommending consideration of an intensive multidisciplinary rehabilitation program for patients with non-radicular low back pain who did not improve with the usual conservative program.

No one type of exercise has shown to be more effective than another.

Regular physical activity and exercise are important parts of a healthy lifestyle. In addition to playing a role in reducing pain and improving function in patients with chronic pain, physical fitness benefits people with arthritis, heart disease and diabetes. It helps with managing high blood pressure, balance problems and difficulty walking.

Refer to the original guideline document for more information on rehabilitation/functional management.

Psychosocial Management with Functional Goals

Chronic pain is frequently associated with psychological problems and even comorbid psychiatric diagnoses. The presence of psychological difficulties should in no way invalidate a patient's complaint of pain nor should it eliminate the possibility that a general medical condition may also be present that is causing the pain. If psychological difficulties or psychiatric comorbidities are found, the patient's treatment plan should include specific steps to address them.

Kidney Disease Improving Global Outcomes (KDIGO)

No applicable guidelines were found.

European Best Practices (EBP)

No applicable guidelines were found.

Caring for Australians with Renal Impairment (CARI)

No applicable guidelines were found.

Post-TEP Public Comment Period*

1. Mahesh Krishnan, MD, DaVita

Mahesh Krishnan, MD, is Vice President of Clinical Innovation and Public Policy at DaVita. He noted that facility burden has increased over time. Dr. Krishnan recommended the use of the KDQOL-36, as it is widely collected among the dialysis setting, and offered to collaborate with CMS and UM-KECC on its validation efforts and with deciding which factors may be modifiable for dialysis population.

2. Eduardo Lacson, MD, Fresenius Medical Care, North America

Dr. Lacson also recommended the use of the KDQOL-36, as it is easy to use and already collected across many facilities. Dr. Lacson also noted that whether the KDQOL-36 is truly actionable, or if changes in functional status based on KDQOL-36 are associated with outcomes has not yet been examined.

** Due to a delay in the posting of the TEP meeting agenda, public attendees were unable to call in to the meeting line until after the meeting discussion had concluded.*

Continuity Assessment Record and Evaluation (CARE) Tool

Information relating to the Care Tool development and testing, as well as the CARE: Home Health Admission Tool, is available here: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>

Short Physical Performance Battery

All of the tests should be performed in the same order as they are presented in this protocol. Instructions to the participant are shown in bold and should be given exactly as they are written in this script.

Now let's begin the evaluation. I would now like you to try to move your body in different movements. I will first describe and show each movement to you. Then I'd like you to try to do it. If you cannot do a particular movement, or if you feel it would be unsafe to try to do it, tell me and we'll move on to the next one. Let me emphasize that I do not want you to try to do any movement that you feel might be unsafe. Do you have any questions before we begin?

Standing Balance Battery

Side-by-side Stand

- **Now I will show you the first movement.** (Demonstrate)
- **I want you to try to stand with your feet together, side-by-side, for about 10 seconds.**
- **You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.**
- *Stand next to the participant to help him/her into the side-by-side position.*
- *Supply just enough support to the participant's arm to prevent loss of balance.*
- *When the participant has his/her feet together, ask, "Are you ready?"*
- *Then let go and begin timing as you say, "Ready, begin."*
- *Stop the stopwatch and say "Stop" after 10 seconds or when the participant steps out of position or grabs your arm.*
- *If the participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.*

Side-by-side stand seconds

Score

Held for 10 seconds	<input type="text"/>	1 point
Not held for 10 seconds	<input type="text"/>	0 points
Not attempted (check reason on page X)	<input type="text"/>	0 points

Semi-Tandem Stand

- **Now I will show you the second movement.** (Demonstrate)

- **I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.**
- **You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.**
- *Stand next to the participant to help him/her into the semi-tandem position.*
- *Supply just enough support to the participant's arm to prevent loss of balance.*
- *When the participant has his/her feet together, ask, "Are you ready?"*
- *Then let go and begin timing as you say, "Ready, begin."*
- *Stop the stopwatch and say, "Stop" after 10 seconds or when the participant steps out of position, or grabs your arm.*
- *If the participant is unable to hold the position for 10 seconds, record result and go on to the gait speed test.*

Semi-tandem stand seconds

Score

Held for 10 seconds	<input type="text"/>	1 point
Not held for 10 seconds	<input type="text"/>	0 points
Not attempted (check reason on page X)	<input type="text"/>	0 points

Tandem Stand

- **Now I will show you the third movement. (Demonstrate)**
- **I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds.**
- **You may put either foot in front, whichever is more comfortable for you.**
- **You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.**
- *Stand next to the participant to help him/her into the tandem position.*
- *Supply just enough support to the participant's arm to prevent loss of balance.*
- *When the participant has his/her feet together, ask, "Are you ready?"*
- *Then let go and begin timing as you say, "Ready, begin."*
- *Stop the stopwatch and say, "Stop" after 10 seconds or when the participant steps out of position, or grabs your arm.*

Full tandem stand seconds

Score

Held for 10 seconds	<input type="text"/>	2 points
Held for 3 to 9.99 sec	<input type="text"/>	1 point

Held for < 3 seconds	<input type="checkbox"/>	0 points
Not attempted (check reason on page X)	<input type="checkbox"/>	0 points

If participant did not attempt test:

- a. Tried but unable
- b. Participant could not hold position unassisted
- c. Not attempted because tester felt unsafe
- d. Not attempted because participant felt unsafe
- e. Participant unable to understand directions
- f. Participant refused.....
- g. Other (specify).....

Total Balance Tests Score: _____

Notes: _____

4-meter Walk Test (usual gait speed)

Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it.

A. First Gait Speed Test

- **This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.**
- *Demonstrate the walk for the participant.*
- **Walk all the way past the other cone [or other end of tape] before you stop. I will walk with you. Do you feel this would be safe?**
- *Have the participant stand with both feet touching the starting line.*

- **When I want you to start, I will say: “Ready, begin.”** When the participant acknowledges this instruction say: “Ready, begin.”
- Press the start/stop button to start the stopwatch when the participant steps over the starting line.
- Walk behind and to the side of the participant. Stop timing when one of the participant’s feet is completely across the end line.

Trial #1 seconds

- **Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course.**
- Have the participant stand with both feet touching the starting line. **When I want you to start, I will say: “Ready, begin.”** When the participant acknowledges this instruction say: “Ready, begin.”
- Press the start/stop button to start the stopwatch when the participant steps over the starting line.
- Walk behind and to the side of the participant.
- Stop timing when one of the participant’s feet is completely across the end line.

Trial #2 seconds

If participant did not attempt or failed:

- a. Participant tried, but unable.....
 - b. Participant could not walk unassisted.....
 - c. Not attempted, tester felt unsafe.....
 - d. Not attempted, participant felt unsafe.....
 - e. Participant refused to attempt the task.....
 - f. Participant unable to understand instructions.....
 - g. Other (specify).....
-

Aids used for this walk:

- a. None.....
 - b. Cane.....
 - c. Other (specify).....
-

What is the time of the faster of the two walks?
If only 1 walk was completed, record that time

seconds

Score

Unable to do the walk	<input type="checkbox"/>	0 points
Time is > 8.70 sec	<input type="checkbox"/>	1 point
Time is 6.21 to 8.70 sec	<input type="checkbox"/>	2 points

Time is 4.82 to 6.20 sec	<input type="checkbox"/>	3 points
Time is < 4.82 sec	<input type="checkbox"/>	4 points

Chair Rise Task (Repeated Chair Stand)

Always use the same chair for this test

- **Let’s do the last movement test. Do you think it would be safe for you to try to stand up from a chair without using your arms?**
- **The next test measures the strength in your legs.** Demonstrate and explain the procedure. **First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest.**
- **Please stand up keeping your arms folded across your chest.** *Record result.*
- *If the participant cannot rise without using arms, say “Okay, try to stand up using your arms.” This is the end of the test. Record result.*

	Yes	No
Safe to stand without help	<input type="checkbox"/>	<input type="checkbox"/>
Results		
Participant stood without using arms	<input type="checkbox"/>	→Go to repeated Chair Stand Test
Participant used arms to stand	<input type="checkbox"/>	→End test; score as 0 points
Test not completed	<input type="checkbox"/>	→End test; score as 0 points

Repeated Chair Stand Test

- **Do you think it would be safe for you to try to stand up from a chair five times without using your arms?** *Demonstrate and explain the procedure.*
- **Please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. I’ll be timing you with a stopwatch.**
- *When the participant is properly seated, say: “Ready? Stand” and begin timing.*
- *Count out loud as the participant arises each time, up to five times*
- *Stop if the participant becomes tired or short of breath during repeated chair stands.*
- *Stop the stopwatch when he/she has straightened up completely for the fifth time.*

Also stop if:

- *Participant uses his/her arms*
- *After 1 minute, if participant has not completed all 5 rises*
- *At your discretion, if concerned for participant’s safety*

If the participant stops and appears fatigued before completing the five stands, confirm this by asking, “Can you continue?”

Number of chair rises.....

Time to complete five stands seconds

If participant did not attempt test or failed:

- a. Participant tried by unable.....
 - b. Participant could not stand unassisted.....
 - c. Participant did not attempted, assessor felt unsafe.....
 - d. Participant did not attempt, he/she felt unsafe
 - e. Participant unable to understand instructions.....
 - f. Participant refused
 - g. Other (specify)
-

Score

Participant unable to complete 5 chair stands, or completed in >60 s	<input type="checkbox"/>	0 points
≥ 16.70 sec	<input type="checkbox"/>	1 point
13.70 to 16.69 sec	<input type="checkbox"/>	2 points
11.20 to 13.69 sec	<input type="checkbox"/>	3 points
≤ 11.19 sec	<input type="checkbox"/>	4 points

Scoring for Complete Short Physical Performance Battery

Total Balance Test score	<input type="checkbox"/>	Points
Gait Speed Test score	<input type="checkbox"/>	Points
Chair Stand Test score	<input type="checkbox"/>	Points
Total Score	<input type="checkbox"/> <input type="checkbox"/>	Points (sum of all)