Establishing a Core Outcome Measure for Fatigue in Patients on Hemodialysis: A Standardized Outcomes in Nephrology–Hemodialysis (SONG-HD) Consensus Workshop Report

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Fatigue is one of the most highly prioritized outcomes for patients and clinicians, but remains infrequently and inconsistently reported across trials in hemodialysis. We convened an international Standardized Outcomes in Nephrology–Hemodialysis (SONG-HD) consensus workshop with stakeholders to discuss the development and implementation of a core outcome measure for fatigue. 15 patients/caregivers and 42 health professionals (clinicians, researchers, policy makers, and industry representatives) from 9 countries participated in breakout discussions. Transcripts were analyzed thematically. 4 themes for a core outcome measure emerged. Drawing attention to a distinct and all-encompassing symptom was explicitly recognizing fatigue as a multifaceted symptom unique to hemodialysis. Emphasizing the pervasive impact of fatigue on life participation justified the focus on how fatigue severely impaired the patient's ability to do usual activities. Ensuring relevance and accuracy in measuring fatigue would facilitate shared decision making about treatment. Minimizing burden of administration meant avoiding the cognitive burden, additional time, and resources required to use the measure. A core outcome measure that is simple, is short, and includes a focus on the severity of the impact of fatigue on life participation may facilitate consistent and meaningful measurement of fatigue in all trials to inform decision making and care of patients receiving hemodialysis.

Complete author and article information (including a list of the SONG-HD Fatigue Workshop Collaborators) provided before references.

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Background

Fatigue is a common symptom that affects 60% to 97% of the hemodialysis population[1] and is associated with cardiovascular events, mortality, and decreased quality of life.[1] The fatigue experienced by patients receiving hemodialysis is believed to be distinct from that associated with other treatment modalities and to be particularly debilitating. This may be directly related to the highly burdensome nature of hemodialysis[2] in combination with other possible causes, including fluid shifts, uremia, anemia, inflammation, metabolic processes, mental health state, and other comorbid conditions.[1] The high prevalence and severe impact of fatigue on overall health and well-being may explain why fatigue is one of the most highly prioritized outcomes for patients receiving hemodialysis and their clinicians.[3,4] Despite this, fatigue remains challenging to manage and under-recognized. Trial-based evidence on the efficacy of interventions for improving fatigue is almost completely lacking,[1,5] which may partly be attributed to problems with how fatigue is measured.

Across hemodialysis trials, fatigue is measured infrequently and inconsistently and with measures that may not capture all aspects of fatigue that have been explicitly identified by patients as important. To date, only 18 of the 123 studies that have reported fatigue as an outcome were randomized trials.[6] Across these studies, 43 different measures have been used and only 20 measures were used in more than 1 trial. The measures vary in dimensionality (ie, different aspects of the fatigue experience), content, and length. Therefore, scores from these measures may each indicate something different about fatigue experienced by patients receiving hemodialysis. This variability in the way fatigue is measured and reported makes it difficult to compare the effect of interventions for fatigue across trials.

Many measures for fatigue have not been specifically developed for patients receiving hemodialysis. For example, the Vitality subscale of the global quality-of-life instrument the 36-Item Short-Form Health Survey (SF-36) is commonly used as a measure of fatigue, but it has not been validated in hemodialysis patients.[6] Evidence for the psychometric robustness of measures is sparse, and whether they capture fatigue accurately and reliably as experienced by patients receiving hemodialysis remains uncertain. Measure properties, including content validity and responsiveness, are not necessarily transferable across different populations, and rigorous validation is required to ensure that the measure is suitable.[7]

Establishing a core patient-reported outcome measure of fatigue that is validated for use in the hemodialysis population will enable accurate assessment and consistent reporting of fatigue to improve the comparability of trials. This will inform decision making and may facilitate the development of targeted interventions to improve this debilitating symptom. The international Standardized Outcomes in Nephrology (SONG) initiative was launched in 2014 to establish a set of core outcomes (and measures) across all stages of chronic kidney disease (CKD) based on the shared priorities of patients, caregivers, and health professionals identified through an explicit consensus process involving nominal group technique, Delphi survey, and a consensus workshop.[3,4,8]

For hemodialysis (SONG-HD), more than 1,200 patients, caregivers, and health professionals from more than 70 countries participated in the process and identified fatigue as 1 of 4 core outcome domains in hemodialysis (along with vascular access, cardiovascular disease, and mortality).[3,8] We convened a stakeholder workshop to inform the development of a core outcome measure for fatigue. Eliciting input from a range of key stakeholders is necessary for ensuring interpretability, acceptability, and feasibility of administering the core outcome measure. The aim of this workshop report is to describe and summarize stakeholder perspectives on the development and implementation of a core outcome measure for fatigue to be used in all trials of patients receiving hemodialysis.

SONG-HD Fatigue Consensus Workshop

Context and Scope

The SONG-HD Fatigue Consensus Workshop was held at Conference Chicago in Chicago, IL, in November 2016. The workshop provided an opportunity for participants to provide input and discuss key considerations for establishing a core outcome measure for fatigue. A systematic review and a survey completed by patients, caregivers, and health professionals identified tiredness, level of energy, and life participation (impact of fatigue on ability to participate in life, ie, usual/daily activities) as the most important dimensions.[6] The survey will be reported separately; however, some findings have been included here to provide context for the workshop discussion. The survey was completed by 505 participants (169 patients and 336 health professionals). Patients all had current or previous experience of hemodialysis ranging from 5 months to 6 years. They were invited through the SONG network. Together, these results will inform the development of a proposed core outcome measure for fatigue.

Attendees and Contributors

Fifteen patients on hemodialysis therapy and caregivers (14 from Chicago and 1 from the United Kingdom) and 42 health professionals (including nephrologists, surgeons, psychologists, dieticians, researchers, nurses, policy makers, and industry representatives) from 9 different countries attended the workshop. Health professionals were purposively identified to include a range of practice locations, clinical experience, and roles. Patients and caregivers were invited by a local SONG-HD fatigue investigator and received reimbursement for parking and public transport. The full list of SONG-HD fatigue workshop attendees and contributors is provided in the Article Information section.

To increase awareness and facilitate implementation of the outcome measure, we invited health professionals with leadership or advisory roles in professional societies (eg, American Society of Nephrology, Australian and New Zealand Society of Nephrology, European Society of Nephrology, and the Asian Pacific Society of Nephrology), regulatory agencies (eg, US Food and Drug Administration and US Centers for Medicare & Medicaid Services), nephrology journals, registries (eg, UK Renal Registry), funding organizations (eg, National Institutes of Health), industry, and guideline organizations (eg, KDIGO [Kidney Disease: Improving Global Outcomes]). We also sought to include health professionals with expertise in patient-reported outcome measures, fatigue, and hemodialysis. Those who were unable to attend in person were asked to provide feedback before the workshop and review and contribute additional perspectives to this report.

Workshop Program and Materials

The workshop program is available as Item S1. Background materials, including results of the systematic review and interim results from the survey, were sent to participants 2 weeks before the workshop. The workshop commenced with short presentations to introduce the SONG initiative, an overview of preliminary results from the systematic review and survey on fatigue, and the objectives and focus of breakout discussions. For breakout discussions, participants were allocated to 5 facilitated groups with 10 to 13 attendees in each. Each group had at least 2 patients and/or caregivers. The groups included multidisciplinary health professionals to promote more dynamic and diverse discussion. Facilitators attended a briefing session and were provided with a detailed run sheet that contained a question guide (Item S2). Examples of questions from frequently used fatigue measures (SF-36, Functional Assessment of Chronic Illness Therapy-Fatigue, and Public Records Online Management Information System [PROMIS]) were given to participants as prompts. Participants in all groups were asked to provide feedback on the interim findings of the survey (ie, the most important dimensions of fatigue), wording for the proposed outcome measure, and implications regarding the development and use of the core outcome measure. All groups reconvened and a representative from each group presented to the broader group the key points from their discussion. This plenary session was facilitated by the workshop Chair (M.U.), who concluded the workshop by summarizing the perspectives, suggestions, and implications raised across all groups.

All discussions were audiotaped and transcribed verbatim. Transcripts were entered into Hyper RESEARCH (ResearchWare Inc; version 3.0) to facilitate coding and analysis of the data. Participants' comments and suggestions regarding the development and implementation of a core outcome