Report of the Standardized Outcomes in Nephrology–Hemodialysis (SONG-HD) Consensus Workshop on Establishing a Core Outcome Measure for Hemodialysis Vascular Access

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Vascular access outcomes in hemodialysis are critically important for patients and clinicians, but frequently are neither patient relevant nor measured consistently in randomized trials. A Standardized Outcomes in Nephrology–Hemodialysis (SONG-HD) consensus workshop was convened to discuss the development of a core outcome measure for vascular access. 13 patients/caregivers and 46 professionals (clinicians, policy makers, industry representatives, and researchers) attended. Participants advocated for vascular access function to be a core outcome based on the broad applicability of function regardless of access type, involvement of a multidisciplinary team in achieving a functioning access, and the impact of access function on quality of life, survival, and other access-related outcomes. A core outcome measure for vascular access required demonstrable feasibility for implementation across different clinical and trial settings. Participants advocated for a practical and flexible outcome measure with a simple actionable definition. Integrating patients' values and preferences was warranted to enhance the relevance of the measure. Proposed outcome measures for function included "uninterrupted use of the access without the need for interventions" and "ability to receive prescribed dialysis," but not "access blood flow," which was deemed too expensive and unreliable. These recommendations will inform the definition and implementation of a core outcome measure for vascular access function in hemodialysis trials.

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

Am J Kidney Dis. 71(5): 690-700. Published online February 22, 2018.

doi: 10.1053/j.ajkd.2017.12.003

Background

A functioning vascular access is a lifeline for patients requiring hemodialysis (HD), but has a high risk of complications.[1] Vascular access complications account for approximately 20% to 30% of hospital admissions for patients on HD and incur substantial health care costs.[2,3] One in every 2 arteriovenous fistulas or grafts will fail to function within the first year of creation and necessitate further interventions for problems such as inadequate maturation, stenosis, or thrombosis.[4–7] Central venous catheters are often required and may be associated with even higher levels of morbidity, mortality, and health care costs.[8,9] Infection, bleeding, and pain during arteriovenous access (fistula or graft) cannulation can cause further stress to patients and their caregivers.[10,11] Improving vascular access outcomes is therefore a critical priority for patients requiring HD, their caregivers, and clinicians.[12]

Many trials have been conducted in an effort to improve vascular access outcomes, but little success has been achieved.[5,13,14] The interpretation and applicability of trial outcomes are limited by the extreme heterogeneity of reported outcome measures, use of outcomes that may not be directly relevant to patients or clinical decision making, and outcome reporting bias.[15] The ability to assess the comparative effects of interventions on vascular access complications has been limited by inconsistent outcome reporting.[4,14,16,17] The need to standardize reporting of critically important outcomes has been widely advocated,[18–21] and there is a growing number of initiatives to establish core outcome sets, defined as an agreed-upon minimum set of standardized outcomes that ought to be measured and reported in all trials for a specific clinical area.[22–26]

The international Standardized Outcomes in Nephrology (SONG) initiative aims to establish a set of core outcome measures across the spectrum of chronic kidney disease based on the shared priorities of patients, caregivers, clinicians, researchers, policy makers, and industry. Consistent reporting of highly relevant core outcomes in clinical trials can help improve the quality, relevance, and comparability of research to inform clinical decision making, inform quality improvement initiatives, and help facilitate measurement of clinical outcomes in everyday practice. The first and current focus of SONG is on establishing a set of core outcomes for HD following established methodology.[12,15,23,26,27] Based on consensus among 1,200 patients, caregivers, and health professionals from more than 70 countries, vascular access has been identified as 1 of 4 core outcome domains in HD (ie, vascular access, fatigue, cardiovascular disease, and mortality).[12,28] The current report focuses on the development of a core outcome measure for vascular access.

The aim of this workshop report is to describe and summarize stakeholder perspectives on the identification and implementation of a core outcome measure for vascular access to be used across all HD trials. This will help ensure that the most relevant and meaningful outcome

measure is selected, address potential challenges, and optimize implementation strategies.

SONG-HD Vascular Access Consensus Workshop

Context and Scope

The international SONG-HD vascular access consensus workshop was convened in Chicago during the American Society of Nephrology Kidney Week Conference in 2016 for stakeholders to discuss the identification and implementation of a core outcome measure for vascular access to be reported in all trials in HD. The top prioritized outcomes were vascular access function and infection based on a systematic review and interim results from an international survey on vascular access outcomes that was completed by patients/caregivers and health professionals.

Participants and Contributors

Patients, caregivers, and health professionals (nephrologists, radiologists, interventionalists, surgeons, nursing and allied health professionals, researchers, and policy makers) with current or previous experience with HD were invited to the workshop. To further enhance successful dissemination and implementation of the vascular access core outcome measure, invitations were extended to representatives of 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 Centers for Medicare & Medicaid Services), nephrology journals, registries, funding organizations (eg, US National Institutes for Health), industry, and guideline organizations (eg, KDIGO [Kidney Disease: Improving Global Outcomes]). In total, 59 participants (11 patients, 2 caregivers, and 46 health professionals) from 12 countries attended the workshop and 25 workshop contributors provided feedback on the workshop materials and preliminary report, but were unable to attend the workshop in person (Table S1). All workshop participants consented to being recorded and listed as investigators and ethics approval was therefore not required for this workshop.

Workshop Program and Materials

The 2-hour workshop was held on November 18, 2016, at Conference Chicago at University Center in Chicago, IL. The workshop program, background material (including examples of outcome measures and validation tools[29]), and interim results were sent to participants 2 weeks in advance. During the workshop, an overview of the SONG-HD Vascular Access Initiative was presented, including interim results from the aforementioned systematic review of vascular access outcome measures and the SONG-HD vascular access survey.

Participants were allocated to 1 of 5 breakout discussion groups. Each group had 10 to 13 members and included 2 to 4 patients or caregivers and at least 1 member of the SONG-HD vascular access working group. The facilitator of each group (C.M.H., A.K.V., B.M., A.T., and E.O.) received a briefing session before the workshop and was provided with a question guide (Item S1). Participants discussed the interim results of the survey (which will be reported separately but are referred to in this report when necessary to provide context for specific statements), potential core outcomes (ie, function and infection), and outcome measures. Examples of outcome measures, measurement properties, and feasibility aspects for the selection of a core outcome measure[29] were provided as prompts. Participants were also asked to discuss strategies for implementing core outcome measures in trials. In the final plenary session, all groups reconvened and a member from each group presented key points from their discussion, which was then summarized by the chair of the workshop (C.M.H.).

All breakout and plenary discussions were audiotaped and transcribed. The transcripts were entered into HyperRESEARCH (ResearchWare Inc; version 3.0.) to facilitate coding and data analysis. From the transcripts, A.K.V. reviewed and analyzed participants' comments and suggestions regarding the development and implementation of a core outcome measure for vascular access in HD. Following the workshop, all participants and contributors received a draft workshop report to provide feedback within a 2-week time frame. Additional comments were integrated into the final report.

Summary of Workshop Discussion

Overall, we identified 5 themes from the discussion: (1) capturing the broad applicability of function, (2) emphasizing experiential relevance and severity, (3) demonstrating feasibility of implementation, (4) ensuring robustness and validity, and (5) integrating patients' values and preferences. Illustrative quotations for each theme are shown in Box 1 and contributions from breakout groups to the respective themes are listed in Table S2. Possible outcome measures discussed during the workshop are provided in Table 1, and recommendations of the consensus workshop are summarized in Box 2.

Capturing the Broad Applicability of Function

Applicable to All Access Types

Function was confirmed by workshop participants to be the most important vascular access outcome, reflecting interim results of the international survey. Participants emphasized that access function was equally relevant to all access types (ie, fistula, graft, and central venous catheter) and contributed greatly to the success of HD. In comparison, although infection was commonly encountered in catheters, it was less so in grafts and fistulas. Therefore, as one health professional put it, "by focusing on infection we will completely miss the boat if we are looking at the full scope of access." Similarly, although cannulation problems were considered a very important outcome by patients and health professionals, this applied only to fistulas and grafts and was therefore deemed unsuitable as a core outcome. Participants