



The Approach to the Psychosocial Evaluation of Cardiac Transplant and Mechanical Circulatory Support Candidates

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Abstract

Purpose of Review We update evidence underlying the recommendations of a 2018 multi-society consensus report regarding the psychosocial evaluation of individuals for cardiothoracic transplantation and mechanical circulatory support (MCS). In the present review, we focus on heart transplantation and MCS.

Recent Findings Expert opinion and new evidence support the inclusion of ten core content areas in the psychosocial evaluation. Prospective data indicate that psychosocial factors can predict post-transplantation/post-implantation outcomes. Such factors include treatment adherence history, mental health and substance use history, cognitive impairment, knowledge about treatment options, and social factors such as socioeconomic status. For other factors (e.g., coping, social support), new evidence is weaker because it derives largely from cross-sectional studies. Concerning evaluation process issues, expert opinion remains consistent with consensus recommendations, but there is a dearth of empirical evidence.

Summary The psychosocial evaluation can identify factors relevant for candidacy for heart transplantation and MCS implantation. It enables the provision of interventions to improve patients' viability as candidates, and facilitates care planning.

Keywords Heart transplantation · Mechanical circulatory support · Psychosocial evaluation · Psychosocial outcomes · Clinical outcomes

Introduction

In 2018, the International Society for Heart and Lung Transplantation (ISHLT), in collaboration with the Academy of

Topical Collection on *Nonpharmacologic Therapy: Surgery, Ventricular Assist Devices, Biventricular Pacing, and Exercise*

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Psychosomatic Medicine (now the Academy of Consultation-Liaison Psychiatry), the American Society of Transplantation, the International Consortium of Circulatory Assist Clinicians, and the Society for Transplant Social Workers, issued a consensus statement delineating 61 specific recommendations for the content and the process of conducting and reporting on the psychosocial evaluation of cardiothoracic transplant candidates and candidates for mechanical circulatory support (MCS) [1•]. The impetus for the statement was the fact that existing ISHLT guidelines already call for a psychosocial evaluation to be completed and for its results to be used to identify factors that serve as contraindications to selection for transplantation or MCS implantation [2–4]. The evaluation is also critical for identifying areas where interventions can be offered to improve patients' viability as transplant or MCS candidates. In addition, it may facilitate the development of plans to address patients' care needs after transplantation or implantation. However, as the consensus statement noted, “in the absence of any previous synthesis of both expert opinion and the empirical literature into a consensus-based, comprehensive set of recommendations for practice, cardiothoracic

transplant and MCS programs have been left to determine their own approach to the psychosocial evaluation...Variability in content and process [of the evaluation] may contribute to inequities in...candidate selection and overall patient care” [1••].

The consensus statement was thus designed to provide guidance and promote consistency across clinical programs by proposing a core set of content domains and processes for conducting the psychosocial evaluation. The recommendations not only incorporated expert opinion and experience but also were based on a comprehensive review of the empirical literature (published as late as mid-2017) documenting associations between psychosocial factors and risks for poor clinical outcomes after transplantation or MCS implantation. Since publication of the consensus statement, additional expert commentary and relevant empirical work have become available. This information helps to address gaps in the

evidence that were noted at the time of the consensus work. In the present paper, therefore, we summarize the 2018 consensus recommendations and provide an update on the evidence supporting the recommendations. We focus on the heart failure literature, considering new data and expert commentary appearing in 2017 through mid-2019 pertaining to psychosocial factors and their assessment in candidates for heart transplantation or MCS.

The Content of the Psychosocial Evaluation

Table 1 summarizes the ten content domains recommended for inclusion in the psychosocial evaluation. These domains cover (a) risk factors for poor outcomes, identified through assessments of history of medical adherence problems, mental health

Table 1 Domains to be assessed in the psychosocial evaluation of heart transplant and MCS candidates

Evaluation domain	Description of the domain
Treatment adherence and health behaviors	Past and current medical adherence; knowledge about current treatment regimen, and willingness to adhere to the post-transplantation/post-implantation regimen
Mental health history	History and current status of mood, anxiety or other disorders, including any thoughts of suicide or self-injury; receipt and response to past or ongoing treatment and willingness to undertake additional treatment; mental health history of family
Substance use history	History and current level of use of all substances, including tobacco, alcohol and both prescription and illicit drugs; diagnosable disorder and any past or ongoing treatment; insight and willingness to undertake additional treatment and supports for maintaining abstinence; substance use history of family
Cognitive status and capacity	Capacity to comprehend information and engage in decision-making discussions with healthcare providers, and evidence of impairments in capacity
Knowledge and understanding of current illness	Knowledge about the course and causes of current illness, limits of currently received treatments, and reasons for referral for transplantation or MCS
Knowledge and understanding of treatment options	Knowledge about risks and benefits of treatment options given patients' severity of illness; understanding about reasons that transplantation or MCS are now being considered
Coping with illness	Response to illness and coping skills and strategies used to manage the illness and its daily impact; evidence of denial of illness severity, prognosis or treatment options
Social support	Availability and willingness of family or other individuals to provide practical and emotional support; understanding of these individuals about the illness and treatment options available, and their role in assisting the patient
Social history	Sociodemographic characteristics including education, literacy and health literacy, occupation, employment history, marital/partnership status, living arrangements, and cultural background including religious/faith practices; financial and medical insurance status; legal issues and any ongoing or past major life stressors
Knowledge about and capacity to operate MCS device	Understanding and capacity to perform basic device operations; evidence of cognitive or physical limitations that would preclude such performance; safety of home environment

See Dew et al. [1••] for 35 specific recommendations regarding content of the domains of the psychosocial evaluation

problems, or substance use problems; (b) factors related to patients' knowledge and understanding of their current health, current treatment, and future treatment options, as well as their capacity to make treatment decisions; (c) factors characterizing patients' psychosocial resources that could mitigate the impact of psychosocial risk factors, including coping skills, social support, and social history; and (d) factors related specifically to MCS candidates' knowledge and capacity to operate the device. Recent expert opinion affirms the importance of the identified content domains [5–9], and recent empirical evidence further supports the relevance of these domains for predicting post-transplantation and post-implantation outcomes. Below, we provide a synopsis of empirical evidence reviewed in the consensus report for each domain and then describe new work published during 2017–2019.

Treatment Adherence and Health Behaviors

Summary of Consensus Report Review Medication nonadherence before heart and other solid organ transplantation is a prime risk factor for post-transplant medication nonadherence, which itself can directly increase the likelihood of post-transplant morbidities and mortality. Heart recipients with histories of nonadherence to other elements of the medical regimen, such as clinical follow-up requirements, have poorer survival rates and are at elevated risk for graft rejection. MCS patients with pre-implantation histories of nonadherence to medical directives, or who are nonadherent to care requirements after implantation, are at risk for medical complications (e.g., pump thrombosis) and poorer health-related quality of life (HRQOL).

Evidence Update We could identify no new prospective studies on the role of pre-transplant nonadherence history. However, new work further indicates the clinical impact of nonadherence after heart transplantation. In a USA national sample, Tumin et al. [10•] reported that not only was immunosuppressant medication nonadherence greatest in adolescent and young adult heart recipients aged 17–24 (compared with younger and older recipients), but also their survival rate was poorest. Interestingly, although nonadherent patients (based on clinician report) had reduced survival time, nonadherence did not completely explain the survival decrement in this age group. The authors suggested that other biological and social factors (e.g., socioeconomic factors, changes in care providers) may also contribute to reduced survival time.

In MCS recipients, Lundgren et al. [11•] examined a range of psychosocial factors assessed before implantation in a single-center study with over 200 patients. A history of medical regimen nonadherence was not associated with 1-year post-implantation survival or number of hospital readmissions after MCS implantation. The authors speculated that individuals with potential psychosocial contraindications may have

been denied MCS implantation, thus reducing the likelihood that pre-implantation psychosocial factors such as nonadherence would be associated with the two post-implantation outcomes.

Mental Health History

Summary of Consensus Report Review Depression and anxiety—the most common psychiatric conditions in transplant and MCS candidates and recipients—both appear to increase risk for post-transplant mortality. The evidence is strongest for depression, with less definitive evidence for anxiety. Depression is also a risk factor for medical nonadherence, and is associated with poorer coping strategies and more medical complications such as infections. Little to no evidence is available concerning the role of other conditions such as bipolar disorder, psychosis, or personality disorder in heart recipients or MCS recipients. However, these disorders may be relevant (e.g., individuals with personality disorders may have less stable social supports). Family mental health history has not been considered in studies of transplant/MCS populations, but such history affects patient risk for mental disorders and is pertinent for identifying appropriate mental health care.

Evidence Update Several single-site studies have focused on heart recipients. Two small investigations (with sample sizes less than 50) reported that patients with elevated pre-transplant depression symptom scores were at higher risk for post-transplant adherence-related problems, including patient perceptions that they faced more barriers to immunosuppressant medication adherence [12], and poorer actual medication adherence [13]. Pre-transplant depression was not related to missing post-transplant clinical follow-up appointments, occurrence of graft rejection, or duration of survival, although it increased patients' risk for rehospitalization [13]. Vitinius et al. [12] found a strong association between pre-transplant anxiety symptoms and post-transplant perceptions of medication adherence barriers, but the association was not statistically significant due to their very small sample size.

In a larger single-site study of 130 heart recipients, Epstein et al. [14] examined whether diagnosable depression or anxiety during the year before heart transplantation predicted time to graft loss (i.e., either death or retransplantation). Neither condition on its own predicted this outcome. However, by 3 years post-transplant, patients who had either condition before transplant (vs. those with no depression or anxiety) were more likely to suffer graft loss. Patients who were comorbid for both conditions were also at increased risk compared with patients who had neither disorder. All such effects dissipated by 5 years post-transplant, suggesting that there may be a time limit to the potency of these pre-transplant risk factors.

In two recent single-site studies of MCS recipients, pre-implantation depressive or anxiety disorders were each

associated with greater risk for rehospitalization in the first 6 months post-implantation [15] and for a greater number of rehospitalizations [11•]. MCS recipients comorbid for both disorders were at particularly high risk for more rehospitalizations [11•], and they also showed elevated heart rate and filling pressures post-implantation [16]. Neither depression nor anxiety (alone or in combination) predicted 1-year mortality [11•]. There was no evidence that other psychiatric disorders (bipolar illness, mania, posttraumatic stress disorder) affected risk for rehospitalization [11•, 15] or mortality [11•].

Substance use History

Summary of Consensus Report Review Tobacco use and alcohol/drug abuse before heart transplantation or MCS implantation are associated with a range of poor post-surgical clinical outcomes. This may be primarily because patients with substance use histories are at risk for relapse to substance use after transplantation or implantation. Tobacco use not only contributes to reduced survival time but increases the risk for cardiac allograft disease, cancers, hypertension, and acute kidney injury in heart recipients, and medical complications in MCS recipients. Alcohol abuse and drug abuse have received limited study in heart recipients, but they increase morbidity and mortality risks in organ recipients in general, and risks for driveline infections, rehospitalizations, and mortality in MCS recipients. Case reports in organ recipients link heavy inhaled cannabis use to increased post-transplant infection risks; associations of cannabis use specifically in heart and MCS recipients have not been reported.

Some studies do not find substance use/abuse to be associated with post-transplant clinical outcomes, perhaps because active substance use is generally a contraindication to transplantation. The shorter the duration of abstinence before organ transplantation, the higher the risk of relapse post-transplant. Duration of abstinence has not been examined in MCS recipients. Finally, family history of substance abuse is a risk factor for relapse to substance use in transplant patients; it likely has a similar role in MCS recipients.

Evidence Update In a small single-center study of heart recipients, Sözen et al. [17] replicated the known association between a pre-transplant history of tobacco use and reduced post-transplant survival time. Some patients smoked post-transplant, which may partially account for the association. A recent systematic review noted that shorter duration of abstinence from smoking before heart transplant (< 6 months in some studies; < 12 months in others) is the most consistent predictor of post-transplant smoking [18••].

Two studies, already described above, also examined the role of pre-implantation tobacco and other substance use in MCS recipients [11•, 15]. Kaiser found no reliable

association of substance abuse (whether licit or illicit) during the 6 months before the pre-implantation psychosocial evaluation with risk for rehospitalization during the first 6 months post-implantation. However, there were few cases with substance abuse in the sample, given that patients were required to demonstrate stable abstinence before MCS implantation. Lundgren et al. found that a pre-implantation history of drug use predicted more post-transplant rehospitalizations, but that tobacco smoking at the time of implantation, previous smoking, and a history of alcohol use were not associated with this outcome. In addition, MCS recipients who smoked at the time of implantation were at increased mortality risk during the first year post-implantation, while past smoking and pre-implantation histories of alcohol or drug use did not affect mortality risk.

Cognitive Status and Capacity to Give Informed Consent

Summary of Consensus Report Review Cognitive impairment is common in patients undergoing evaluation for heart transplantation and/or MCS. However, unless patients have dementia or other such permanent, major brain diseases, cognitive impairment may not preclude their ability to give informed consent. Cognitive functioning can, but does not always, improve with transplantation/implantation.

Greater cognitive impairment, assessed either before or after heart transplantation, predicts poorer survival. In patients undergoing evaluation for heart transplantation, it is concurrently associated with poorer medical adherence. MCS patients with poorer cognitive functioning have poorer HRQOL. Although such patients also show less confidence in managing their medical regimen, their actual level of medical adherence may not be adversely affected, perhaps due to assistance from family and other caregivers.

A small literature suggests that patients with intellectual disabilities can achieve medical outcomes similar to other patients after organ transplantation provided they have adequate social supports. No studies have examined medical adherence and other outcomes after MCS implantation in such patients.

Evidence Update We could identify no new evidence for heart recipients. For MCS recipients, Lundgren et al. [11•] performed relatively extensive pre-implantation cognitive testing and found that, across a variety of cognitive domains, greater impairment was associated with a longer length of hospital stay after implantation. It was not associated with number of rehospitalizations or 1-year post-implantation mortality. The authors speculated that poorer cognitive functioning may limit patients' ability to absorb new information about post-implantation care requirements, resulting in more time needed to prepare for hospital discharge.

Knowledge and Understanding of Illness

Summary of Consensus Report Review Patients' knowledge about advanced heart disease course and prognosis is often incomplete, and lack of adequate understanding of these issues is associated with poorer self-management of the medical regimen. Conversely, greater knowledge is associated with better self-care, better HRQOL, and fewer adverse outcomes, including fewer hospital readmissions and reduced mortality in heart and MCS recipients.

Evidence Update In a multicenter study of heart failure patients, Ambardekar et al. [19] found that patients were likely to underestimate their mortality risk, based on follow-up data on actual survival time. Patients' estimates about prognosis were unrelated to future events such as receiving a transplant or MCS, requiring inotrope support, or being rehospitalized. These findings suggest that patients may not have optimal understanding of their health status, which could preclude fully informed decision-making about their illness and treatment needs.

Knowledge and Understanding of Current Treatment Options

Summary of Consensus Report Review Patients often have an incomplete understanding of possible treatment options, their risks and benefits, and the self-care responsibilities that would come with transplantation/MCS implantation. Patients' attitudes and emotional reactions (e.g., fears, expectations) can be at least as important as knowledge in influencing decision-making about transplantation and/or MCS implantation. Patients may feel considerable conflict and uncertainly when making choices regarding transplantation, MCS, or other medical options. When patients understand their heart failure treatment options and also have their decisional conflict reduced (e.g., through use of decision aids), they feel more prepared, involved, and satisfied with the decision-making process. Although not examined in heart transplant or MCS patients, studies in chronic disease populations show that greater understanding and lower decisional conflict can improve medication adherence and clinical outcomes.

Evidence Update No new studies have focused on heart transplantation. However, two multisite clinical trials examined decision aid interventions in patients undergoing evaluation for MCS. Kostick et al. [20•, 21] tested a decision aid comprised of written information, plus educational videos available on a website. Compared with patients receiving usual care and education, the decision aid group had higher knowledge levels at 1-week post-intervention, although knowledge declined by 1-month post-intervention. The intervention did not affect whether patients agreed to MCS implantation, but

among those receiving MCS, decision aid patients had higher life satisfaction levels.

Allen et al. [22••] compared decision quality among patients receiving usual care and education vs. those receiving a decision aid including clinician-directed education, a video, and written materials. They defined decision quality as a combination of both greater knowledge and greater concordance between patients' values and their treatment choice. The decision aid group showed more improvement in knowledge from pre- to immediately post-intervention, and greater concordance between patients' values and their treatment choice at 1-month post-intervention. There was no impact on secondary outcomes such as depressive symptoms, perceived stress, and overall HRQOL at a 6-month follow-up. The authors did not specifically compare these latter outcomes across patients who had vs. had not received MCS by this time point.

Finally, two qualitative studies suggest that patients can feel forced to make quick decisions regarding whether to accept MCS, with little time for deliberation [23]. Moreover, patients' views about treatment choices may change after experience with a given treatment [24]. Specifically, Wilhelms et al. [24] found that, although MCS candidates felt they would prefer to undergo heart transplantation rather than MCS, patients who already had MCS were often ambivalent about possible heart transplantation, citing fears about additional lifestyle changes and reporting that they were satisfied with their "new normal" lifestyle with MCS. These findings suggest that patients' decision support needs may vary across different stages of their treatment trajectories.

Coping With Illness

Summary of Consensus Report Review Patients' coping styles and specific strategies for coping with health issues are associated with psychosocial outcomes before and after heart transplantation and MCS implantation. For example, in heart recipients, positive expectations and feelings of self-efficacy and personal control predict better subsequent mood, medical adherence, and HRQOL. Conversely, use of passive or avoidant coping strategies, denial, and venting of negative emotions are associated with negative outcomes both before and after transplantation, including depression, anxiety, pain, fatigue, and impaired HRQOL. Such strategies can also increase mortality risks after heart transplantation.

A small literature in MCS patients indicates that feeling more capable of managing one's self-care regimen is associated with better medical adherence and HRQOL. Failure to psychologically accept the need for MCS, inability to problem-solve while living with MCS, and use of denial and avoidant coping strategies are associated with greater self-care difficulties and poorer HRQOL.

Evidence Update There have been no new prospective studies of pre-transplantation/pre-implantation coping on post-surgical outcomes. Three studies have examined cross-sectional associations between post-transplantation/post-implantation coping strategies and other variables including perceived stress, depressive symptoms, and immunosuppressant medication adherence. To the extent that coping strategies are relatively stable, the studies suggest that some coping strategies may be preferable to others for possibly promoting positive psychosocial outcomes. Thus, a relatively small single-site study reported that heart recipients' perceived stress and depressive symptoms were higher if they had lower feelings of self-efficacy in managing their self-care needs [25]. A small two-site study found that, although HRQOL was not associated with coping strategies, perceived stress was higher among MCS recipients who used avoidant and self-blame strategies for coping with health problems [26]. A large international multisite study reported that immunosuppressant medication adherence was poorer among heart recipients who had a lower sense of self-efficacy in managing their medication regimen, although this association was reduced once other psychosocial factors were controlled [27].

Social Support

Summary of Consensus Report Review No matter how social support is defined (e.g., by network size or by perceived quantity or quality of support), it has been linked to many outcomes after organ transplantation, including heart transplantation. Poorer support before or early after transplantation increases risk for post-transplant medication nonadherence, relapse to substance use, mental health problems, poorer HRQOL, graft failure, and mortality. MCS patients with poorer social support have higher risks of rehospitalization and mortality. Finally, social supports can mitigate, or buffer against, the potentially deleterious effects of other psychosocial risk factors for poor outcomes in heart transplantation, including cognitive impairment, intellectual disability, and mental health problems.

Evidence Update The most noteworthy new investigation is a small single-site prospective study reporting that MCS recipients with better pre-implantation caregiver support (defined as a better quality patient-family caregiver relationship) showed greater improvement in HRQOL from pre- to post-implantation [28•]. The three cross-sectional studies that examined coping (see discussion above) also examined associations between heart and MCS recipients' social support and other psychosocial outcomes. The large multisite study [27] did not find heart recipients' general perceptions of emotional and practical support to be associated with better immunosuppressant adherence. However, patients receiving a specific type of support—namely, having someone to help read health-related materials—were more likely to be adherent.

Miliniak et al. [25] found that both emotional and practical support were associated with lower perceived stress and less depression in heart recipients. In MCS patients, better overall social support (regardless of the specific type of support) was not only associated with lower perceived stress but buffered the association between perceived stress and HRQOL (i.e., the association was weaker when support was better) [26].

A new meta-analysis examined social support in relation to medication adherence and clinical outcomes across all types of solid organ transplantation [29••]. Better social support was associated with better clinical outcomes (e.g., less graft loss, morbidity, mortality). Moreover, this finding held when analysis was limited to studies of heart recipients. However, there was no reliable association between social support and medication adherence. Because only one study of heart recipients considered the social support-medication adherence association (and found a marginally significant effect), meta-analysis in this subtype of organ recipients was not possible. Moreover, the authors noted that their analyses collapsed across different sources of support (e.g., from family vs. friends) and there is evidence in cardiothoracic transplantation that family support is relatively more important for reducing medication nonadherence risk.

Social History

Summary of Consensus Report Review The importance of taking a complete social history derives largely from expert experience rather than empirical evidence. Empirical evidence exists for three areas: patient educational attainment, socioeconomic status (SES), and lifetime exposure to traumatic events. First, in heart transplantation, lower educational attainment, literacy, and health literacy can reduce patient understanding of illness and treatment options, and can increase risk for HRQOL impairment, medical nonadherence, morbidity, and mortality. Some studies do not find these effects; inconsistent findings may stem from differences between programs in the pre-transplantation patient education process.

Second, heart recipients with lower SES, including those with public health insurance, are at greater risk for poorer outcomes in the USA. These outcomes include medical nonadherence, rehospitalization, morbidity, and mortality. The impact of SES—particularly insurance status—on outcomes is unlikely to be due solely to the organization and financing of healthcare in the USA because linkages of SES to health outcomes exist even in settings of universal health care coverage. There is inconsistent evidence on whether SES is associated with outcomes during MCS.

Finally, lifetime exposure to traumatic events increases risk for adverse health outcomes in the general population (likely due to its more proximal impact on mental health and substance use). Thus, this factor should be assessed before transplantation/implantation to facilitate appropriate care planning.

Evidence Update Considerable new work has been published. In heart recipients, Wayda et al. [30•] measured SES with a composite of education, insurance, and neighborhood characteristics in a large national sample. Even after demographic and clinical factors were controlled, low SES was associated with graft loss (defined as death or retransplantation), graft rejection, rehospitalization, infection, and indicators of medication nonadherence. A smaller single-site study failed to find that SES (assessed by median household income and public vs. private health insurance) increased the risk of severe graft rejection once demographic and clinical factors were controlled [31]. However, the size of the SES-rejection association was similar to that obtained by Wayda et al., suggesting that this latter study was underpowered.

The contribution of SES to MCS outcomes remains unclear. Two relatively small single-site studies were unable to demonstrate significant associations between SES indicators (patient education, income, financial resources, type of health insurance, rural vs. urban place of residence) and clinical outcomes once confounding factors were controlled. The outcomes examined included length of hospital stay after implantation [32], rehospitalization [15, 32], MCS complications [32], and mortality [32, 33].

Among other sociodemographic characteristics, new evidence suggests that African American heart recipients are at higher risk of graft loss [30•], medication nonadherence [10•], and mortality [10•] compared with white recipients. Wayda et al. [30•] suggested that the race effect on graft loss may be due in part to biological factors (e.g., increased sensitization and peak panel of reactive antibodies), especially given that the association was independent of SES. Moreover, the race-medication nonadherence association may have arisen due to factors correlated with race such as health literacy [34]. Breathett [35] noted that presumed medication nonadherence in African Americans may reflect immunosuppressant metabolism factors rather than failure to take medications.

Finally, two studies provide novel data on the role of heart recipients' pre-transplant employment. Both used the same USA national database. Ravi et al. [36•] found that patients recorded as “working” pre-transplant had better post-transplant survival, no matter whether work status was considered at time of listing or time of transplant. This effect was maintained even when a range of demographic and health-related factors were controlled. Rudasill et al. [37•] focused on work status at transplant and obtained similar results. However, the association became nonsignificant after patients' insurance status (private vs. other sources) was controlled. It is not clear whether patients who were working did so to retain insurance coverage or whether other factors were involved. However, both studies suggest the need for additional research on the role of work status, especially in the context of other social factors that may predict transplant outcomes.

Knowledge About and Capacity to Operate MCS Device

Summary of Consensus Report Review Despite limited research, it is well-known that MCS patients must follow a complex medical regimen and family members or other support persons provide critical assistance. Cognitive limitations and difficulties with adhering to requirements for operating their MCS device increase patients' risk for poorer HRQOL. Family caregiver assistance may help to overcome patient problems with device operation and regimen adherence.

Evidence Update No studies have evaluated factors directly affecting self-care outcomes. However, Casida et al. [38, 39] surveyed MCS patients who participated in online support groups and found that 90% or more of patients had completed a skills demonstration test before initial hospital discharge, received “hands on” instruction in MCS device management, and received additional written resources. Nevertheless, only 75% of patients felt prepared at discharge for their responsibilities in daily self-care and MCS operation. The authors did not examine whether feeling prepared resulted in better self-care or ability to operate the device. However, because additional findings indicated that 52% to 84% felt that they needed re-training and/or needed frequent MCS follow-up about home care issues, it seems likely that self-care management outcomes in these individuals had room for improvement.

The Psychosocial Evaluation Process

The psychosocial evaluation is best considered as a process rather than a one-time event, and the 2018 consensus recommendations reflect this perspective. The process elements and a summary of recommendations are provided in Table 2, and focus on (a) who should conduct the evaluation, (b) considerations in performing the evaluation itself and determining when additional consultation is needed, (c) strategies for reporting evaluation findings, and (d) issues to consider in referring patients for interventions and monitoring intervention outcomes so that psychosocial contraindications to transplantation/MCS implantation may be removed or mitigated. The optimal scenario is for each program to develop its own protocol incorporating these recommendations, as well as any additional procedural elements that the program deems essential.

The consensus document noted that most of the process recommendations were based on expert opinion and experience. There was a dearth of relevant empirical work. Recent expert opinion continues to support the 2018 process recommendations [6, 7]. Empirical evidence remains limited for most of the elements in Table 2. An exception pertains to work examining the use of templates and checklists for summarizing the psychosocial evaluation. Several recent reports have

Table 2 The psychosocial evaluation process in heart and MCS candidates

Process factor	Summary of strategies to be employed
Evaluator qualifications and experience	Require evaluator to have training in a healthcare discipline related to evaluation content, with appropriate credentialing; provide initial ongoing training and educational opportunities.
Performance of the psychosocial evaluation	Inform patient of purpose of evaluation and conduct it in a language in which the patient can fully participate (with interpreter support as needed); directly interview the patient when possible with arrangements for reevaluation if needed to update information; collect collateral information especially if patients cannot fully participate in the evaluation due to medical factors, and interview the patient's primary support person to ascertain that individual's understanding of the patient's treatment options and needs.
Use of templates or checklists to assist the evaluator	Consider whether standard templates or checklists would be helpful to ensure that the evaluator addresses and records information about all domains to be covered in the evaluation.
Screening for capacity to give informed consent	If cognitive impairments are suspected, employ a screening tool to aid in assessment of status and make decisions about need for referral for additional evaluation; if deemed necessary, ensure that formal assessment is completed in order to determine capacity to give informed consent and make medical decisions.
Communicating evaluation results to transplant/MCS team	Prepare a written summary of the evaluation for the patient's record, noting all findings and recommendations; note whether any psychosocial risk factors were identified and whether and how they may be ameliorated by interventions or treatments; participate in transplant/MCS team meetings in order to communicate evaluation findings and recommendations.
Coordinating psychosocial interventions and assessment of progress	Coordinate or identify other team member who will coordinate and monitor intervention progress and determine whether interventions have been successful; determine whether re-evaluation is needed once interventions have been undertaken.

See Dew et al. [1••] for 26 specific recommendations regarding content of the domains of the psychosocial evaluation

evaluated whether such instruments allow for quantitative risk scores to be generated that reliably predict psychosocial and clinical outcomes after heart transplantation or MCS implantation.

Before summarizing this new evidence, we note that the consensus document recommended that evaluators consider using templates and checklists because these tools can have heuristic value in assisting evaluators to systematically collect and report evaluation information. However, the consensus group stated that (a) there were insufficient data to assert that any one tool was superior to others and (b) they did not endorse the use of any tool to create an overall numerical “score” or “rating” of a patient’s psychosocial suitability for transplantation or MCS implantation, given very limited evidence of such metrics’ validity for predicting outcomes.

New evidence affirms the consensus group’s position; predictive validity remains tenuous. In brief, three checklist tools exist and cover similar areas (see a recent review [40]): the Transplant Evaluation Rating Scale (TERS), the Psychosocial Assessment of Candidates for Transplantation (PACT), and the Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT). There are seven recent studies.

In the three studies of heart recipients (one using the TERS, one using the PACT, and one using the SIPAT), patients identified as being at “high psychosocial risk” based on their score on the rating tool were more likely post-transplant to experience incident depressive disorder [41], be nonadherent to clinical follow-up appointments [42], and possibly to perceive more barriers to immunosuppressant medication adherence [12]. However, this latter finding held only at one of two assessed time points. These studies found no predictive effects on many other psychosocial outcomes, including post-transplant medication adherence, substance use, problems with social support, financial barriers to care, mental health problems in general, or incident anxiety disorders in particular [41, 42]. There were also no reliable relationships to clinical outcomes including graft rejection, length of hospital stay after transplant, time to rehospitalization, total hospital days, or number of rehospitalizations [41, 42]. Two studies found no effect on mortality [40, 41]; the third study reported equivocal evidence, depending on the method used to calculate “high-risk” using the psychosocial rating tool score [12].

Four studies used rating tools with MCS patients (one used the PACT, three used the SIPAT). None considered post-

implantation psychosocial outcomes. Many clinical outcomes were examined, with little evidence that psychosocial risk scores served as predictors. First, none of the studies found that high psychosocial risk scores increased the likelihood of post-implantation mortality [43–46]. Second, three reports [43–45] examined post-implantation morbidities (e.g., infections, renal failure, right heart failure, neurological events, hemolysis, bleeding, thrombotic events, arrhythmias). One study found an association between high psychosocial risk and bleeding [43] but none of the studies found associations with any other type of morbidity [43–45]. Third, three studies examined healthcare use [43–45]. Psychosocial risk was not associated with likelihood of post-implantation rehospitalization [43–45], or with length of hospital stay after implantation, days in the intensive care unit, more urgent care or emergency department visits, or number of days hospitalized during follow-up [45]. Finally, in a report defining a composite adverse event outcome (hospitalization, device exchange and death), no association was found between high psychosocial risk and time to first adverse event [46]. However, patients with high psychosocial risk scores had a greater cumulative number of adverse events and fewer days alive outside of the hospital.

In sum, the recent studies yield, at best, equivocal findings regarding the predictive abilities of psychosocial risk rating tools. However, all were single-site reports, most samples were relatively small, and follow-up periods were generally brief. Moreover, the patients highest in psychosocial risk likely did not undergo transplantation/implantation, leading to relatively few patients with high-risk scores in the samples. This would reduce the studies' ability to detect associations between risk status and the outcomes. At least in heart transplantation, the psychosocial rating tools may be slightly more helpful in predicting poorer psychosocial than clinical outcomes, although the few reliable effects each appear in only a single investigation and were not replicated across them.

Conclusions

The psychosocial evaluation is an integral component of the overall medical assessment of individuals under consideration for heart transplantation or MCS implantation. The evaluation's content is necessarily comprehensive and, as such, provides information essential for candidate selection as well as for identifying areas warranting intervention to improve patients' viability as candidates, and for overall care planning. Expert opinion and empirical evidence published since the 2018 consensus recommendations support the content areas delineated in the consensus document. New studies provide further information on psychosocial factors' ability to predict post-transplantation/post-implantation psychosocial and clinical outcomes. The new evidence appears strongest for

treatment adherence history, mental health history, substance use history, cognitive impairment, knowledge about one's illness and options for treatment, and social factors such as SES. The evidence for these areas comes from either prospective studies, retrospective studies that examine prospectively collected data (i.e., the risk factors were recorded before the outcomes), or clinical trials attempting to intervene on putative risk factors. For other psychosocial factors (e.g., coping, social support), the new evidence is more limited because it derives largely from cross-sectional studies and the direction of associations between variables cannot be determined.

An important contribution of the 2018 consensus document was an extensive set of recommendations on the process of conducting and reporting on findings from the psychosocial evaluation. Although expert opinion continues to support the recommendations, there is little new empirical evidence regarding process issues. New reports focus on whether the tools that evaluators could use during the evaluation may also be used to generate numerical indicators of psychosocial risk. Results suggest that the approach of numerically "adding up" risk across the key content domains—at least in terms of the metrics utilized with currently available tools—does not yet add value to the prediction of outcomes. We suggest that effort may be better directed to the type of research we reviewed earlier regarding the specific impact of each separate domain of the evaluation (e.g., medical adherence history, mental health history) on risk for poor post-transplantation/post-implantation outcomes.

Overall, future research is needed to explore why certain psychosocial characteristics predict poor psychosocial or clinical outcomes, i.e., the mechanisms by which risk is increased. Determination of key explanatory variables could lead to the development of more effective strategies to intervene on psychosocial risk factors and thereby promote better patient outcomes. Evidence-based recommendations for the content and the process of the psychosocial evaluation will ultimately be further enriched if psychosocial factors serving as contraindications to heart transplantation and MCS are not only identified but can be more effectively controlled or eliminated.

Compliance With Ethical Standards

Conflict of Interest Mary Amanda Dew's effort in preparing this report was supported in part by grant R01 AG047416 from the National Institute on Aging, Rockville, MD. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. Kathleen L. Grady has been a speaker for the American Heart Association and the Heart Failure Society of America. She and Annemarie Kaan are members of the Board of Directors, ISHLT. All of the authors were members of the leadership group of the 2018 consensus document [1••].

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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