AMA Journal of Ethics®
November 2019, Volume 21, Number 11: E974-979

POLICY FORUM

Why Quality-of-Life Data Collection and Use Should Be Standardized When Evaluating Candidates for Hand Transplantation

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Abstract

This article argues for 3 mutually reinforcing interventions in the field of hand transplantation (HTx): (1) collection of qualitative data about hand transplant recipients' subjective quality of life (QoL) outcomes, (2) multicenter standardization of data collection, and (3) use of data to develop evidence-based, standardized protocols for HTx candidate evaluation and information disclosure. These interventions are needed to improve candidate evaluation and informed consent processes in HTx, wherein the highly personal nature of desired outcomes justifies holding a candidate's consent to a standard approaching authenticity rather than the usual minimal standard of being informed and voluntary.

Quality-of-Life Data

Because the primary goal of hand transplantation (HTx) is maximizing transplant recipients' functional, emotional, and social quality of life (QoL),[1,2] it is ethically, clinically, and scientifically critical to assess the potential for HTx to improve a recipient's QoL. As with all QoL interventions, patients' subjective experiences are relevant to assessing whether an intervention achieves its aim. If HTx generally or routinely fails to improve hand transplant recipients' QoL, it might not (yet) be ethical to offer it, especially outside of experimental protocols. Collecting QoL outcomes data is thus critical for justifying HTx as a medical intervention and for providing accurate and salient information to candidates considering the procedure. Without QoL data, candidates are unable to evaluate the risk-benefit ratio and thus to give informed consent. In addition to collecting QoL data, 2 other interventions are needed to improve candidate evaluation and informed consent processes: multicenter standardization of QoL outcomes data collection and use of QoL data to develop evidence-based, standardized protocols for HTx candidate evaluation and information disclosure. This article discusses these interventions and argues for holding a candidate's consent to a standard approaching authenticity rather than the usual minimal standard of being informed and voluntary.

Data Collection Standardization

Collection of QoL outcomes data is needed to identify factors that predict successful HTx outcomes—including not only graft survival, functionality, and absence of comorbidities, but also improved QoL—and to use these factors to develop tools for use in candidate evaluation. There are no standardized guidelines for HTx candidate evaluation, and existing health status survey instruments (eg, the SF-36 by Ware and Sherbourne[3]) fail to capture the existential, identity-related, and interpersonal aspects of recipients' pre- and post-HTx life experiences that are critical to their QoL. Professionals who conduct psychosocial evaluations (PSEs) of HTx candidates and evaluate their social support and financial preparedness need to know which factors are useful for predicting positive HTx outcomes, including improved QoL. Beyond improving recipients' capacities to accomplish activities of daily living, goals such as the ability to feel a child's skin, to look "normal," to feel whole, or to return to vocational or avocational activities might be of critical importance to particular candidates.[4,5] Assessing rehabilitation demands prior to HTx is also important. For example, some candidates might welcome the sense of control their rehabilitation regimen can offer, but others might find it onerous or a necessary evil at best. The subjective, individualized, even idiosyncratic nature of QoL benefits to hand transplant recipients suggests that an outcomes registry that includes QoL outcomes data is needed as a first step to develop an evidence base. An evidence base is critical not only for developing standardized instruments for evaluating candidates but also for improving information disclosure and decision making during informed consent processes.

A number of specific psychosocial domains are emerging as important and predictive of posttransplant outcomes.[6,7,8,9] Yet key psychosocial challenges faced by HTx candidates and recipients are not well characterized despite some reports of QoL improvements[10] and negative psychosocial sequelae, including reactivation of psychiatric disorders, family discord, substance dependency issues, nonadherence, and dissatisfaction.[6] Currently, there are no psychosocial instruments designed specifically for use in this unique population.[6,10,11,12,13] In consequence, a variety of PSE protocols are used by individual transplant centers (see Supplementary Appendix). Standardized collection of subjective QoL outcomes data would likely increase confidence in research findings on factors predictive of improved QoL. Yet no standardized guidelines for collection of QoL outcomes have been developed for HTx.

Qualitative research is often used to generate hypotheses, theme-based criteria, or questions to be used when standardizing assessment or survey instruments.[14,15] Qualitative research on patient-reported subjective dimensions of QoL should be used to develop new standardized—perhaps even quantitative—assessment tools for evaluating candidates and collecting post-HTx data about QoL. Findings from such standardized assessments should in turn be used to improve informed consent and decision-making processes for HTx candidates.

Fairness and Candidate Evaluation Standardization

Given the subjective, individual, and even idiosyncratic nature of QoL benefits candidates seek from HTx, each candidate must be carefully evaluated. Indeed, concern for patients' well-being supports developing evidence-based, standardized instruments and protocols for PSE that would facilitate transfield comparison of surgical, functional, and QoL outcomes. Standardization of evaluation instruments and processes can also promote fairness in several ways.

The ethical importance of treating similar patients similarly supports incorporating standardized candidate evaluation (including PSE) instruments into all vascular composite allograft programs.[13] Standardization would minimize the impact of personal biases (eg, about whether a candidate is likeable, sympathetic, or "difficult") on evaluation. Moreover, developing and employing standardized assessment tools based in part on factors of subjective importance to past candidates and recipients would mitigate the impact of scientific biases in candidate evaluation.

Standardization of candidate evaluation processes through use of standardized assessment tools would enable—indeed, force—HTx programs to clarify whether a candidate's ineligibility for HTx is based on factors that are team focused, candidate focused, or a combination of the two. Different programs might justifiably accept or reject candidates based in part on a team's particular expertise, but a lack of "fit" between a candidate and a transplant team should result in referral to another HTx program rather than a declaration that the candidate is ineligible for HTx.

Fairness and concern for patients' well-being also requires that decisions about candidates' access to HTx be based on their medical needs and desired medical and QoL outcomes. History or presence of psychopathology, for example, should not categorically exclude HTx candidates; instead, this factor should be taken to indicate that additional support might be necessary during and following HTx. Indeed, a candidate's psychopathology is particularly relevant when the need for HTx derives from significant trauma. Similarly, while strong social support is associated with positive HTx outcomes, fairness demands that this fact not lead to the categorical exclusion of candidates lacking traditional familial support structures. Instead, teams should recognize the possibility that less traditional support structures may be adequate or should work creatively to identify social services to fill this need.

Authenticity of Informed Consent

Improving informed consent should be a goal of developing and using standardized tools to both evaluate HTx candidates and assess recipients' QoL outcomes. Informed consent requires disclosure of potential risks and benefits of an intervention and its alternatives, including refusal of treatment. Clinicians are obligated to help HTx candidates accurately assess this information and

consider the relevance of both risks and benefits to their specific situation. Some candidates might overestimate HTx's potential to improve their QoL or underestimate demands of long-term rehabilitation and life-long immunosuppression regimens, for example. Other candidates might not fully comprehend the nature and scope of surgical risks or the potential for re-amputation or re-transplantation in case of graft loss.[4,6] A standard outcomes-assessment tool (based on previous HTx candidates' and recipients' expectations for and concerns about HTx as well as their QoL reports) could help clinicians better inform and support candidates' decision making.

An evidence base of subjective QoL outcomes could put flesh on the skeleton of the HTx risk-benefit ratio, which currently focuses on functionality in terms of activities of daily living and clinical risks. For some HTx candidates, factors such as aesthetics, identity, a sense of wholeness, facility performing specific functions, and relative facility interacting with others with a prosthesis vs HTx may be equally or more important than facility performing activities of daily living. Candidate evaluation and informed consent must elicit HTx candidates' personal goals and expectations, and candidates must be informed about the likelihood of their being met.

Given the subjective, individualized—even idiosyncratic—nature of QoL benefits candidates seek from HTx, there should be a strong correlation between these potential benefits and candidates' values, deeply held preferences, and specific goals. Therefore, the informed consent process should go beyond ensuring that the candidate's decision is informed and voluntary, which are the typical requirements for informed consent.[16] Instead, the candidate's decision should approach the ideal of authenticity—that is, it should be reflective of the candidate's personality, character, deeply held values, and view of a life worth living. By providing data about the subjective QoL outcomes of HTx and seeking a consent decision that is authentic, clinicians can help ensure that candidates' decisions promote their well-being as they themselves define it and that HTx achieves its goal of improving recipients' functional, emotional, and social quality of life.

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Citation
AMA J Ethics. 2019;21(11):E974-979.

DOI
10.1001/amajethics.2019.974.

Conflict of Interest Disclosure
The author(s) had no conflicts of interest to disclose.

The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

ISSN 2376-6980