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Discussion: A Methodology For Determining Standard Of Care Status For a New Surgical Procedure: Hand Transplantation:

Breidenbach WC, Meister EA, Turker T, Becker GW, Gorantla VS, Levin LS

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Breidenbach et al. proposed a methodology for determining standard of care for surgical procedures and determine that for hand transplantation “*there is sufficient positive outcome results and stakeholder acceptance for some to consider hand transplant standard of care.*” (1)

The authors advocate determining standard of care for surgical procedures by assessing “*acceptance by stakeholders*” (e.g. regulatory stakeholders to include governing and insuring bodies and treatment stakeholders to include patients and physicians) and that “*the number of concurring stakeholders determines the strength of the claim for standard of care.*” (1) To assess acceptance by stakeholders, the authors generated a set of questions and suggest that standard of care can be inferred by the number of positive responses. Based on a literature review and a companion article by the authors, they determine that hand transplantation is in public demand, accepted within the academic surgical community, ethical, medically successful, and has support from regulatory stakeholders, therefore indicating a movement towards standard of care.

Despite the liberal use of the term in the literature, there is no universal definition of medical standard of care (2). The authors specifically defined in this paper the absence of discussion of legal standard of care, which is firmly established in tort law, and used to identify a breach of duty (3). The historical roots and evolution of legal standard of care provide an interesting contrast to the authors’ concept of medical standard of care. Legal standard of care was formerly established based on custom (i.e. what is typically done). Through landmark cases, the judicial system altered the definition to “*what is customarily done plus anything that seems reasonable.*” (3) A modern definition is “*that which a minimally competent physician in the same field would do under similar circumstances.*” (3)

Therefore, legal standard of care indicates what reasonable physician should be providing to their patients, as determined through a centralized process (the courts). Conversely, as the authors explained, establishing medical standard of care involves a pluralistic, systemic, and

often contentious process involving all healthcare stakeholders. Whereas legal standard of care applies more broadly to physicians, the concept of medical standard of care may vary depending on expertise and experience. Therefore, the authors' conclusion could have merit in that "*some*" may consider hand transplantation standard of care.

Before accepting the authors' conclusion, we must examine the evidence. The authors' proposed methodology for evaluating standard of care is novel, comprehensive, and useful for facilitate discussions on standard of care. However, the argument for hand transplantation as standard of care is tempered by the substantial subjectivity of the authors' conclusions, and highlights the inadequacies of the methodology. The literature on hand transplantation is sparse, and therefore it remains difficult to draw meaningful conclusions or assumptions on stakeholder acceptance. For example, there is no convincing evidence that treatment stakeholders, arguably the stakeholders of greatest importance, accept hand transplantation as standard of care (4). The majority of hand surgeons remain skeptical and the literature on public demand is conflicting.

Furthermore, there is little effort to discuss contradictory opinions that may be less supportive of hand transplantation. Understated within the article is the lack of available data regarding the socioeconomic impact of hand transplants (5). The cost-effectiveness of a non-lifesaving surgical procedure is critically important within a health system transitioning into value-based medicine (5), especially when a less expensive, safer alternative exists (i.e. prosthesis). Although regulatory stakeholders have provided funding for hand transplantation, this does not inherently indicate a financially beneficial procedure from a public health or patient standpoint. Additionally, the single incremental cost-utility study did not support hand transplantation as standard of care, and the calculations of the cost of hand transplantation may have substantially underestimated the cost of the procedure (6, 7).

In regards to outcomes after hand transplantation, the authors elected to compare outcomes, such as graft survival, against solid organ transplantation. For some readers, the statistical or theoretical comparison between an elective, quality of life improving procedure versus a life sustaining or prolonging procedure may be conceptually difficult. For example, the authors, in discussing risk versus reward stated, "*a majority would rather have bilateral hand transplants and be on dialysis as opposed to a kidney transplant but have no hands*". (1) Considering that the all cause 1-year mortality rate for patients in their first year of hemodialysis is approximately 20% within the United States, this comparison seems misleading (8).

Despite the shortcomings, the authors propose a novel argument that hand transplantation as standard of care is being accepted by a subset of stakeholders. Declaring medical standard of care on the foundation of unempirical evidence and without sufficient literature support appears premature.

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