Remove Clinical Experience Pathway for Non-board Certified Key Personnel at Head and Neck, and Upper Limb Transplant Programs

Sponsoring Committee: Vascularized Composite Allograft (VCA) Transplantation Committee

Policy/Bylaws Affected: OPTN Bylaws, Appendix J (Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs)

Public Comment: January 25, 2016 to March 25, 2016

Effective Date: September 1, 2018

Problem Statement

In the fall of 2014, the VCA Committee drafted a proposal for more robust training and experience requirements for key personnel of VCA transplant programs. After being distributed for public comment in the spring of 2015, the OPTN/UNOS Board of Directors approved the proposal in June 2015. These requirements include clinical experience pathways that could allow a surgeon who did not possess board certification in a specified medical specialty to apply to be the primary transplant surgeon of a head and neck or an upper limb transplant program. The approved language includes a provision for this clinical experience pathway in lieu of board certification to expire on September 1, 2018. This proposal removes this pathway from the Bylaws.

Summary of Changes

The changes to OPTN Bylaws, Appendix J includes removing the clinical experience pathway for a surgeon who is not board certified to qualify as a primary transplant surgeon of a head and neck or upper limb transplant program.

What Members Need to Do

Current Requirements: Transplant hospitals requesting approval for a primary transplant surgeon of a head and neck or upper limb transplant program must meet the current membership requirements in Appendix J. Currently, specific American Board of Medical Specialties (ABMS) certification is not required to qualify to be the primary transplant surgeon of a head and neck or upper limb transplant program.

Requirements as of September 1, 2018: Transplant hospitals with prior approval for a head and neck or upper limb transplant programs that have a primary transplant surgeon without AMBS certification in an identified specialty must submit that individual for approval under the September 1, 2018 requirements. A surgeon who does not possess specified AMBS certifications will not be qualified to be the primary transplant surgeon of a head and neck or upper limb transplant program. If a transition in primary transplant surgeon occurs in a period immediately prior to September 1, 2018, UNOS staff may advise you to carefully consider these new requirements before applying. These more detailed requirements are outlined in the policy notice regarding changes to OPTN Bylaws, Appendix J.3 (Primary VCA Transplant Surgeon Requirements).
Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is struck through.

A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

In addition to the requirements as described in section J.3 above, the surgeon for an upper limb transplant program must meet both of the following:

1. Must meet at least one of the following:
   a. Have current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for an additional 12-month period.
   b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of the following relevant clinical experience:
      i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
      ii. Pre-operative evaluation of at least 3 potential upper limb transplant candidates.
      iii. Acted as primary surgeon of at least 1 upper limb transplant.
      iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

   The multi-organ procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for upper limb transplant procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

   If a primary surgeon qualified under 1.b leaves the transplant program, the replacement for this surgeon must meet the requirements of 1.a. As of September 1, 2018, pathway 1.b will no longer be available and all primary surgeons must meet the requirements of 1.a.

2. Completion of at least one of the following:
   a. A fellowship program in hand surgery that is approved by the MPSC. Any Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program is automatically accepted by the MPSC.
   b. A fellowship program in hand surgery that meets all of the following criteria will also be accepted:
      i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
      ii. The program is located at an institution that has a proven commitment to graduate medical education.
iii. The program director must have current certification in the sub-specialty by the American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or American Board of Surgery.

iv. The program should have at least 2 physician faculty members with hand surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.

v. The program is at a hospital that has affiliated rehabilitation medicine services.

vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

c. At least 2 years of consecutive and independent practice of hand surgery and must have completed a minimum number of upper limb procedures as the primary surgeon according to Table J-1 below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the date of the procedure and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.

<table>
<thead>
<tr>
<th>Type of Procedure</th>
<th>Minimum Number of Procedures</th>
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<tbody>
<tr>
<td>Bone</td>
<td>20</td>
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<tr>
<td>Nerve</td>
<td>20</td>
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<tr>
<td>Tendon</td>
<td>20</td>
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<tr>
<td>Skin or Wound Problems</td>
<td>14</td>
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<tr>
<td>Contracture or Joint Stiffness</td>
<td>10</td>
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<tr>
<td>Tumor</td>
<td>10</td>
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<tr>
<td>Microsurgical Procedures</td>
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<tr>
<td>Free flaps</td>
<td>10</td>
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<tr>
<td>Non-surgical management</td>
<td>6</td>
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<tr>
<td>Replantation or Transplant</td>
<td>5</td>
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Table J-1: Minimum Procedures for Upper Limb Primary Transplant Surgeons

B. Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

In addition to the requirements as described in section J.3 above, the transplant surgeon for a head and neck transplant program must meet both of the following:

1. Must meet at least one of the following:
   a. Have current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months
to allow time for the surgeon to complete board certification, with the possibility of renewal for an additional 12-month period.

b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of the following relevant clinical experience:
   
i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
   
ii. Pre-operative evaluation of at least 3 potential head and neck transplant candidates.
   
iii. Acted as primary surgeon of at least 1 head and neck transplant.
   
iv. Post-operative follow up of at least 1 head and neck recipient for 1 year post-transplant.

The multi-organ procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for head and neck procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

If a primary surgeon qualified under 1.b leaves the transplant program, the replacement for this surgeon must meet the requirements of 1.a. As of September 1, 2018, pathway 1.b will no longer be available and all primary surgeons must meet the requirements of 1.a.

2. Completion of at least one of the following:

   a. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that is approved by the MPSC. Any ACGME–approved fellowship program is automatically accepted by the MPSC.

   b. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that meets all of the following criteria:

      i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.

      ii. The program is at an institution that has a proven commitment to graduate medical education.

      iii. The program director must have current certification in the sub-specialty by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery.

      iv. The program should have at least two physician faculty members with head and neck surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.

      v. The program is at a hospital that has affiliated rehabilitation medicine services.

      vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.
c. At least 2 years of consecutive and independent practice of head and neck surgery. The surgeon must have completed at least 1 face transplant as primary surgeon or first-assistant, or a minimum number of head and neck procedures as the primary surgeon according to Table J-2 below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon and the medical record number, Donor ID, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

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<thead>
<tr>
<th>Type of Procedure</th>
<th>Minimum Number of Procedures</th>
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<tbody>
<tr>
<td>Facial trauma with bone fixation</td>
<td>10</td>
</tr>
<tr>
<td>Head or neck free tissue reconstruction</td>
<td>10</td>
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