

# EVIDENCE-BASED GUIDELINES AND MEASURES

## Evidence-Based Performance Measures: Quality Metrics for the Care of Patients Undergoing Breast Reconstruction

Michele A. Manahan, M.D.  
William A. Wooden, M.D.  
Stephen M. Becker, M.D.  
Jason R. Cacioppo, M.D.  
Stephen B. Edge, M.D.  
Amanda C. Grandinetti, M.P.H.  
Diedra D. Gray, M.P.H.  
Susan O. Holley, M.D., Ph.D.  
Nolan S. Karp, M.D.  
Ergun Kocak, M.D.  
Roshni Rao, M.D.  
Gedge D. Rosson, M.D.  
Jaime S. Schwartz, M.D.  
Thomas J. Sitzman, M.D.  
Hooman T. Soltanian, M.D.  
Sarvam P. TerKonda, M.D.  
Anne M. Wallace, M.D.

*Baltimore, Md.; Indianapolis, Ind.;  
Alcoa, Tenn.; Buffalo and New York,  
N.Y.; Arlington Heights, Ill.; Raleigh,  
N.C.; Cincinnati and Cleveland, Ohio;  
Dallas, Texas; Beverly Hills and La  
Jolla, Calif.; and Jacksonville, Fla.*

**Summary:** The American Society of Plastic Surgeons commissioned the Breast Reconstruction Performance Measure Development Work Group to identify and draft quality measures for the care of patients undergoing breast reconstruction surgery. Two outcome measures were identified. The first desired outcome was to reduce the number of returns to the operating room following reconstruction within 60 days of the initial reconstructive procedure. The second desired outcome was to reduce flap loss within 30 days of the initial reconstructive procedure. All measures in this report were approved by the American Society of Plastic Surgeons Breast Reconstruction Performance Measures Work Group and the American Society of Plastic Surgeons Executive Committee. The Work Group recommends the use of these measures for quality initiatives, Continuing Medical Education, Maintenance of Certification, American Society of Plastic Surgeons' Qualified Clinical Data Registry reporting, and national quality reporting programs. (*Plast. Reconstr. Surg.* 140: 775e, 2017.)

**T**he American Society of Plastic Surgeons assembled the Breast Reconstruction Performance Measure Development Work Group to identify and draft quality measures for the care of patients who undergo breast reconstruction. The goal of the Work Group was to draft measures to improve the quality of care and outcomes for

breast reconstruction patients. The Work Group was tasked with developing measures that reflected the most rigorous clinical evidence that addressed areas in need of performance improvement. Each one of the Breast Reconstruction Measures supports at least one of the Institute of Medicine's six aims for health care quality improvement (i.e., safe,

*From Johns Hopkins University; the Indiana University Health University Hospital; the Community Health Network; the East Tennessee Medical Group; the Roswell Park Cancer Institute; the New York University School of Medicine; the American Society of Plastic Surgeons; the Women's Health Alliance; the Midwest Breast & Aesthetic Surgery; the Cincinnati Children's Hospital Medical Center; the Cleveland Medical Center; the University of Texas Southwestern Medical Center; the Beverly Hills Breast and Body Institute; the University of California San Diego; and the Mayo Clinic Florida.*

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effective, patient centered, timely, efficient, and equitable).<sup>1</sup>

The goal of the Work Group was to develop performance measures based on processes, structures, and outcomes to achieve high-quality care. Desired outcomes for breast reconstruction patients include reduction of reoperations and revision operations, reduction of complications, identification and reduction of barriers in access to care, encouragement of a multispecialty approach to breast reconstruction, promotion of shared decision-making, and continuous improvement in quality of life.

### Scope and Intended Users

The American Society of Plastic Surgeons encourages the use of these measures by plastic surgeons and other health care professionals. These performance measures can be implemented into quality improvement, Continuing Medical Education, Maintenance of Certification, and national quality reporting programs to facilitate practitioner- and system-level quality improvement. Ultimately, the use of these measures should support better outcomes for breast reconstruction patients. These draft measures have been designated for accountability, as they are intended to be tested for scientific acceptability.

### Diversity of Breast Reconstruction Outcomes Literature

Breast reconstruction after mastectomy encompasses a diverse range of surgical techniques: autologous free or pedicled tissue transfer of fasciocutaneous or musculofasciocutaneous flaps from a variety of donor sites including the abdomen, back, and legs; autologous fat grafting in series; and silicone or saline internal prostheses, with all of these techniques able to be considered in immediate, staged with tissue expander,

or delayed fashion. Further diversity is introduced into the field by consideration of unilateral versus bilateral reconstructions, revision operations, possible use of acellular dermal matrix products and different implant types, varied neoadjuvant and adjuvant oncology treatments, and mastectomy techniques such as nipple-sparing procedures. Outcomes may be assessed on diverse aspects such as preoperative workup and decision-making, associated costs, appearance, function, absence of complications, and patient report of satisfaction.

Studies generally support the importance of breast reconstruction after mastectomy. Atisha et al. demonstrated through patient-reported outcomes that women who underwent autologous tissue reconstruction reported the highest breast satisfaction, whereas women undergoing mastectomy without reconstruction reported the lowest satisfaction.<sup>2</sup> Alderman et al., among others, suggest that women who underwent immediate reconstruction were significantly more satisfied with their surgical treatment decision compared with those who underwent mastectomy only.<sup>3</sup> Other literature demonstrates that women who underwent mastectomy with reconstruction reported better quality of life compared with women who underwent mastectomy only. These outcomes included higher satisfaction with breasts, psychosocial well-being, and sexual well-being.<sup>4</sup>

Beyond the fairly robust and consistent body of literature supporting the validity of breast reconstruction in general, the diversity of the field is revealed through the diversity of outcomes reported. Even a review of the most recent literature characterizes the difficulty of standardization of expectations in breast reconstruction. Wade et al. have noted that bilateral deep inferior epigastric perforator flaps have higher rates of complications and flap failure compared with unilateral reconstructions in their series of over 500 flaps.<sup>5</sup> Several studies have demonstrated differences in reconstruction rates and choices of reconstruction types between races and ethnicities.<sup>6,7</sup> Berlin et al. have demonstrated racial and ethnic variations in clinical and patient-reported outcomes in breast reconstruction.<sup>8</sup> Pittman et al., among others, have demonstrated differences in clinical outcomes and complications with use of different types of acellular dermal matrices.<sup>9,10</sup> There is no clear consensus on the risk level associated with the use of acellular dermal matrix.<sup>11</sup>

Pirro et al. show differences in patient satisfaction with different types of reconstruction.<sup>12</sup> Regarding timing, Susarla et al. showed that although single-stage reconstruction (direct-to-implant) is associated

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with higher sexual well-being and satisfaction, it is more likely to require additional operative revisions compared with two-stage prosthetic-based reconstruction.<sup>13</sup> Complications and increased patient age at the time of reconstruction may decrease satisfaction. Furthermore, patients with a prophylactic mastectomy are more likely than those with a therapeutic mastectomy to be dissatisfied when complications arise.<sup>14</sup> The body of literature is vast documenting potential differences in expectations based on the specific details of each reconstruction.

## METHODS

American Society of Plastic Surgeons members were invited to apply to the Work Group by means of Society e-mail and fax communication. All applicants were required to submit an online conflict-of-interest disclosure form for membership consideration. Members of the American Society of Plastic Surgeons Quality and Performance Measurement Committee reviewed and selected Work Group members to ensure a diverse representation of U.S. regions, practice type (i.e., large multispecialty group practice, small group practice, solo practice, and academic practice), experience in clinical research, and evidence-based medicine expertise. Five stakeholder organizations, including the American Society of Breast Surgeons, the American College of Radiology, the American Society of Clinical Oncology, Susan G. Komen for the Cure, and the American Board of Plastic Surgery were also invited to participate in the measure-development process. Each organization nominated one member from their respective organization to serve on the Work Group.

The technical specifications drafted for this performance measurement set were drafted as registry specifications, because many American Society of Plastic Surgeons members are in solo and small group practices and have not yet implemented electronic health records. Electronic health record specifications may be added after confirmation of the inclusion of these measures.

For performance measure exceptions, the American Society of Plastic Surgeons uses the American Medical Association Physician Consortium for Performance Improvement exception criteria, which are divided by medical, patient, and system reasons.<sup>15</sup>

### Other Potential Measures

The Breast Reconstruction Performance Measure Development Work Group considered

developing several additional measures for this patient population. The draft measures that were not fully developed are included below.

#### Capsular Contracture

This measure was originally in the draft measures document. It measured rates of capsular contracture in breast reconstruction by means of expander or implant in patients who present with capsular contracture for which medical and/or surgical intervention is recommended within 12 months of the primary breast reconstruction procedure. The measure was removed from this current measure set because there is not clear evidence that providers can prevent capsular contracture.

#### Shared Decision-Making

This draft measure focused on informing patients of specific risks and was excluded because a discussion of risks and benefits would be included in the informed consent process.

#### Care Coordination

The care coordination measure would have focused on highlighting the importance of a multidisciplinary team coordinating patient care. The Work Group came to consensus that this would be an alternate measure if one of the prioritized measures was not feasible.

#### Risk Assessment

The Work Group was unable to achieve consensus on a validated risk assessment tool to be used in this measure.

#### Reconstruction Options

This draft measure would have focused on promoting access to care in the rural environment. This would have been operationalized by using zip codes. The draft measure could not be created because data collection was not feasible.

#### Treatment Planning

This measure would have encouraged operations to be completed in a specific amount of time, but Work Group members did not reach consensus on an optimal surgical time.

#### Direct-to-Implant Reconstruction

The Work Group concluded that direct-to-implant reconstruction is not always appropriate and there is a question of how large the gap in care may be.

### Functional Status

The Work Group was unable to achieve consensus on a validated functional status tool to be used in this measure.

### Cost of Care

Staff referred the Work Group to the recently endorsed National Quality Forum Cost Measure and suggested not creating a new cost measure unless it could be harmonized.

### Clinical Evidence Base

Performance measure development is a part of the American Society of Plastic Surgeons Evidence-Based Medicine Initiative. Ideally, clinical practice guidelines serve as the foundation for the development of performance measures. However, systematic literature reviews and individual publications also support the Breast Reconstruction Performance Measures. A number of clinical practice guidelines have been developed for the treatment of postmastectomy breast cancer patients. These provide recommendations for the treatment and management of the phases of treatment for this patient population. The Work Group also used data from the American Society of Plastic Surgeons Tracking Operations and Outcomes for Plastic Surgeons database for the 2014 year. (See Appendix, Supplemental Digital Content 1, which show the 2014 Tracking Operations and Outcomes for Plastic Surgeons complications data on implant-based breast reconstruction procedures. *CPT*, Current Procedural Terminology; *DVT*, deep venous thrombosis, <http://links.lww.com/PRS/C430>. See Appendix, Supplemental Digital Content 2, which shows the 2014 Tracking Operations and Outcomes for Plastic Surgeons complications data on autologous breast reconstruction procedures. *CPT*, Current Procedural Terminology; *DVT*, deep venous thrombosis, <http://links.lww.com/PRS/C431>.) The Tracking Operations and Outcomes for Plastic Surgeons is a national database that tracks plastic surgery procedures and outcomes. Clinical practice guidelines from the following organizations were reviewed during the measure-development process: the American Society of Plastic Surgeons,<sup>16</sup> the American College of Radiology,<sup>17</sup> and the National Comprehensive Cancer Network.<sup>18</sup>

## QUALITY MEASURES

### Breast Reconstruction: Return to the Operating Room

#### Description

This group consisted of female patients aged 18 years and older who underwent breast

reconstruction and had an unplanned second operation on the reconstruction site within 60 days of the primary breast reconstruction procedure.

#### Exclusions and Exceptions

There were no exclusions and no exceptions.

#### Supporting Evidence, Rationale, and Opportunities for Improvement

From 2007 to 2011, the number of new cases of breast cancer was 124.6 per 100,000 women per year (based on cases and deaths). The number of deaths was 22.2 per 100,000 women per year. These rates are age-adjusted. Approximately 12.3 percent of women will be diagnosed with breast cancer at some point during their lifetime, based on 2009 to 2011 data. In 2011, there were an estimated 2,899,726 women living with breast cancer in the United States.<sup>19</sup> Increasing numbers of these patients are undergoing breast reconstruction, with 109,256 undergoing a reconstructive procedure in 2016 based on American Society of Plastic Surgeons statistics.<sup>20</sup> Therefore, the population chosen for the measure is sizable.

Complications requiring return to the operating room were chosen as an outcomes measure based on the presumed burden when these occur. For example, one type of complication, surgical-site infection, contributes to extended hospital stays and increased health care costs. In addition, surgical-site infections can compromise the outcome of reconstruction and may result in decreased patient satisfaction.<sup>21</sup> The infection rates in implant-based reconstruction vary from 5.1 to 28 percent. Risk factors for infection include the following: presence of cellulitis, inpatient procedures, irradiation, contralateral breast surgery, breast size, tobacco use, obesity, patient age older than 65 years, and the use of acellular dermal matrix. Clinical manifestations of infection include erythema, swelling, fever, and the presence of pathogens through periprosthetic culturing.<sup>22</sup>

The measure was designed to more globally encompass potential complications known to occur after breast reconstruction, rather than to focus solely on any one type of complication. The following defines complications in the referenced clinical guideline recommendation: "Complications, although not limited to, most commonly include the following: infection, hematoma, seroma, wound dehiscence, skin flap necrosis, expander/implant loss, malposition, expander/implant deflation, capsular contraction, hypertrophic or keloid scarring, and venous thromboembolism disease" (Level II Evidence, Recommendation Grade: B).<sup>16</sup>

Given current limitations in defining, tracking, and recording mild manifestations of complications, the measure was defined to include complications requiring return to the operating room. The complexity of tracking and attributing complications is summarized in the following statement, taken verbatim from the referenced clinical guideline recommendation: “Evidence is varied and conflicting on the association between postoperative complications and the timing of postmastectomy expander/implant breast reconstruction and is often confounded by the use of radiation. The inconsistent research findings

and a lack of evidence should alert physicians to evaluate each case individually” (**Level II, III, IV Evidence, Recommendation Grade: C**).<sup>16</sup> Therefore, effort was directed toward development of clear measure language that would be able to be consistently understood and used.

**Breast Reconstruction: Flap Loss**

**Description**

This group consisted of female patients aged 18 years and older who underwent breast reconstruction by means of autologous reconstruction (not including latissimus flap) with or without a

**Table 1. Specifications: Return to the Operating Room\*†**

Numerator	Patients who have an unplanned second operation on the reconstruction site within 60 days of the primary breast reconstruction procedure. Definitions: Unplanned second operation: For the purposes of this measure, an unplanned second operation may include revisions, corrective surgery, and/or surgery due to complications of the primary breast procedure. Captured by workflow within the ASPS QCDR.
Denominator	All female patients aged 18 yr and older who had breast reconstruction Female and Age ≥ 18 yr and CPT and HCPCS code for encounter: 19357, 19357–50, 19340, 19340–50, 19342, 19342–50, 19361, 19361–50, 19364, 19364–50, 19367, 19367–50, 19368, 19368–50, 19369, 19369–50, S2068
Denominator exclusions	None
Denominator exceptions	None
Measure purpose	Accountability
Type of measure	Intermediate outcome
Level of measurement	Physician level
Care setting	Ambulatory Inpatient
Data source	Clinical data registry

ASPS, American Society of Plastic Surgeons; QCDR, Qualified Clinical Data Registry; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.

\*American Society of Plastic Surgeons 5: Measure Specifications—Breast Reconstruction: Return to Operating Room

†Measure description: Percentage of female patients aged 18 years and older who underwent breast reconstruction who have an unplanned second operation on the reconstruction site within 60 days of the primary breast reconstruction procedure.

**Table 2. Specifications: Flap Loss\*†**

Numerator	Patients who present with flap loss within 30 days of the primary breast reconstruction procedure. Definition: Flap loss: For the purposes of this measure, flap loss is a loss of tissue due to infection or vascular compromise, requiring removal of the tissue flap. Total flap loss is greater than 90% of a flap. Partial flap loss is less <10–90% of a flap. Captured by workflow within the ASPS QCDR.
Denominator	All female patients aged 18 yr and older who had breast reconstruction by means of autologous reconstruction (not including latissimus flap) with or without a tissue expander or implant Female and Age ≥ 18 yr and CPT and HCPCS code for encounter: 19340, 19340–50, 19364, 19364–50, 19367, 19367–50, 19368, 19368–50, 19369, 19369–50, S2068
Denominator exclusions	None
Denominator exceptions	None
Measure purpose	Accountability
Type of measure	Outcome
Level of measurement	Physician level
Care setting	Ambulatory Inpatient
Data source	Clinical data registry

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.

\*American Society of Plastic Surgeons 6: Specifications—Breast Reconstruction: Flap Loss

†Measure description: Percentage of female patients aged 18 years and older who underwent breast reconstruction by means of autologous reconstruction (not including latissimus flap) with or without a tissue expander or implant who present with flap loss within 30 days of the primary breast reconstruction procedure.

tissue expander or implant who present with flap loss within 30 days of the primary breast reconstruction procedure.

### Exclusions and Exceptions

There were no exclusions and no exceptions.

### Supporting Evidence, Rationale, and Opportunities for Improvement

From 2007 to 2011, the number of new cases of breast cancer was 124.6 per 100,000 women per year (based on cases and deaths). The number of deaths was 22.2 per 100,000 women per year. These rates are age-adjusted. Approximately 12.3 percent of women will be diagnosed with breast cancer at some point during their lifetime, based on 2009 to 2011 data. In 2011, there were an estimated 2,899,726 women living with breast cancer in the United States.<sup>19</sup> Increasing numbers of these patients are undergoing breast reconstruction, with 109,256 undergoing a reconstructive procedure in 2016 based on American Society of Plastic Surgeons statistics, with 20,650 of those being autologous reconstructions.<sup>20</sup> Therefore, the population chosen for the measure is sizable.

Flap loss is well-established as a significant complication endpoint. In general, rates are low, but the morbidity associated with this complication is high. A variety of literature explores potential factors that may impact this. Myriad factors have been assessed for impact on flap viability, and a few include unilateral versus bilateral reconstructions,<sup>5</sup> tamoxifen use,<sup>23</sup> operative factors such as blood loss and length of surgery,<sup>24</sup> and flap characteristics.<sup>25,26</sup> However, much accepted variability in practice exists, as consistent findings with high levels of evidence are rare.

The 30-day time point was chosen based on the generally held belief among Work Group members that nonviable tissue occurring as a result of the flap surgery would fully manifest within 30 days postoperatively. Flap loss has been left to the practitioner to define, as data are lacking regarding clinical significance associated with percentages of nonviable transferred tissue. It is hoped that use of this measure over time will facilitate data collection and analysis that may continue the current literature trends that attempt to improve recommendations that can guide physicians in practice choices that may improve outcomes.

*Michele A. Manahan, M.D.*

Department of Plastic Surgery  
Johns Hopkins University School of Medicine  
601 North Caroline Street, 8th floor  
Baltimore, Md 21287  
mmanahan@jhmi.edu

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