



Massachusetts Board of Registration in Medicine
Quality and Patient Safety Division

Betsy Lehman Center for Patient Safety and Medical Error
Reduction

**REPORT OF THE
EXPERT PANEL TO REVIEW IMMEDIATE
IMPLANT-BASED BREAST RECONSTRUCTION
FOLLOWING MASTECTOMY FOR CANCER**

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FOREWORD

As a state agency with regulations requiring hospitals to report quality data and unexpected patient outcomes, we must continually ask ourselves “what are we learning from these reports, and how can we use that knowledge to improve quality and patient safety?”

As an example, our Quality and Patient Safety (QPS) Division received a number of reports describing patients who had developed infections following mastectomy and breast reconstruction. The procedures had been performed in compliance with evidence-based surgical and infection-control practices, and yet the reporting hospitals and the QPS Division felt compelled to explore the issues further. Is infection associated with post mastectomy breast reconstruction a developing trend, are these cases a “canary in the coal mine?” Can we reduce and possibly even eliminate these complications? Can we take steps to ensure that breast cancer patients have the information they need to weigh the risks and benefits of breast reconstruction?

Those questions prompted the institution of a joint project with the Betsy Lehman Center for Patient Safety and Medical Error Reduction that called upon patients and experts in the field to investigate how health care facilities and providers can improve the treatment and overall experience of women who are faced with decisions about mastectomy and breast reconstruction. Not only has this project resulted in recommendations meeting that goal, it has demonstrated how a regulatory mandated reporting system that is non-punitive, collaborative and transparent can be effective in improving the quality of patient care.

I would like to express my deepest gratitude to the members of the *Expert Panel to Review Immediate Implant Based Breast Reconstruction following Mastectomy for Cancer* for their dedication to this project. All members of the Panel were volunteers who participated out of their interest in the well-being of breast cancer patients. I especially want to thank the project co-chairs, Dr Margaret Duggan and Dr. Bernard Lee, who provided the leadership and guidance necessary for the Panel members to accomplish their goals. I would also like to thank the Task Group leaders, who spent tireless hours coordinating the research and preparing their reports.

As with any project, the “behind-the-scenes” support is crucial for success. To those who provided that support, I express my appreciation: Tracy Gay, *Director of the QPS Division*; Maureen Keenan, *Project Director*; Dr. Suyog Kamatkar, *Research Coordinator*; Ellen Fulton, *Medical Librarian*; and Jennifer Sadowski, *Administrative Assistant*. I also wish to express my gratitude to the QPS Division quality analysts, Barbara Watts and Jane Mihalich, for identifying post-mastectomy breast reconstruction as a “quality” issue that deserved attention.

The leadership at the Massachusetts hospitals performing post-mastectomy breast reconstruction procedures are to be commended for their commitment to their patients, transparency and willingness to work with the QPS Division and Betsy Lehman Center.

Finally, we were only able to accomplish this project through collaboration with the leadership at the Department of Public Health and the Betsy Lehman Center, and for that I am grateful.

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PREFACE

Since the early 20th century, the incidence of breast cancer has been steadily rising. In the United States, 207,000 women will have received a new breast cancer diagnosis in 2010 and 13% will be diagnosed in their lifetime. Even with proper screening, a large portion of these women will require mastectomy for their treatment and many more will choose mastectomy to diminish the risk of local recurrence.

Many women who undergo mastectomy will also choose to have immediate implant-based reconstruction. Aesthetic results have improved dramatically with the FDA re-approval of silicone implants in 2006 and introduction of a variety of implant types and acellular dermal matrix material. Between that time and now, a number of surgical procedures have been developed such that implant-based reconstruction should be viewed more as a category of reconstruction rather than a singular procedure. Technical performance of these procedures varies from surgeon to surgeon and from institution to institution.

In early 2010 the Quality and Patient Safety Division of the Massachusetts Board of Registration in Medicine and the Betsy Lehman Center for Patient Safety and Medical Error Reduction convened a statewide multidisciplinary expert panel to look at the dynamic changes in this field. The goal was to identify best practices in implant-based reconstruction and to make recommendations for future practice and data collection.

The thirty-eight member panel was comprised of plastic surgeons, surgical oncologists, radiation oncologists, medical oncologists, quality and regulatory experts, chiefs of service, nurses and patients. They represented fifteen academic and community hospitals statewide. The panel members were divided into five groups, with representation by each discipline, each with a specific task, which included: (1) reviewing the available data related to the surgical procedure and its various permutations; (2) looking at pre operative and post operative practices that can be employed to decrease risk of infection and other post operative complications; (3) identifying the various approaches to reconstruction and the benefits versus the risks of each; (4) determining the critical elements in effective education for patients facing such a complex process; (5) exploring how to broaden the ongoing data collection to identify best practices going forward as this type of procedure continues to evolve.

The full panel met a number of times to discuss the project as a whole, and to hear and discuss reports from the task groups. Each group, after reviewing the pertinent literature and discussing various practical approaches submitted a written report of their findings. There was significant cross over between the groups and surprising agreement amongst the participants. The following is the report generated by this work. Each group struggled with the lack of strong prospective data, but this manuscript represents the best available information and should be seen as a starting point in developing or maintaining a robust breast reconstruction program.

The work of the expert panel will be ongoing in a number of ways. A concerted effort is being made to improve data collection statewide so that in the future we may revise and improve recommendations based on prospectively collected data. A number of panel members are exploring options to develop a breast reconstruction data repository. The patient education group is working toward developing a tool to be used by patients to better understand their options and how to best choose a provider and procedure.

We hope you will use this report in designing or maintaining your breast reconstruction program and that you will be willing to be a part of our statewide effort at data collection.

Sincerely

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I. BACKGROUND

The Quality and Patient Safety (QPS) Division of the Massachusetts Board of Registration in Medicine has statutory responsibility for the oversight of patient safety and quality improvement activities in Massachusetts hospitals. In this role, the QPS Division, through a confidential reporting system, reviews semi-annual reports from hospitals describing their quality improvement activities, and “Safety and Quality Review” reports describing unexpected patient outcomes. The QPS Division works collaboratively with hospitals to improve the quality of care statewide.

Between 2007 and 2008, the QPS Division reviewed seven Safety and Quality Review reports involving breast cancer patients, who had developed infections following breast reconstruction performed at the time of mastectomy. The examination of these cases led to a review of the scientific literature. While research studies had been conducted in this field, they were primarily retrospective and institutionally based. The QPS Division could not identify any definitive, evidenced-based guidelines for breast reconstruction following mastectomy for cancer.

The QPS Division conducted a confidential survey of Massachusetts hospitals and learned that infections associated with breast reconstruction procedures appeared to be a systemic versus isolated practice issue. The infections reported in the survey primarily involved patients who had undergone immediate reconstruction with the use of implants, tissue expanders, and acellular dermal matrix. While the QPS Division’s findings were based on survey results, without formal data collection and analysis, it was believed that they identified an area of practice that should be further explored. Members of the QPS Division consulted local experts in breast reconstruction and hospital quality leaders, who expressed support for a quality initiative. They also explored the possibility of a collaborative project with the *Betsy Lehman Center for Patient Safety and Medical Error Reduction* (“the Betsy Lehman Center”), the Massachusetts organization that is a clearinghouse for the development, evaluation and dissemination of best practices for patient safety.

The incentive for a quality project to review this area of practice was supported by the American Cancer Society statistics on the incidence of breast cancer. With the exception of cancer of the skin, breast cancer is the most frequently diagnosed cancer in women. Statistics for 2010 estimated 207,090 new cases of invasive breast cancer and 54,010 additional cases of in situ breast cancer.¹ Also, the number of breast reconstruction procedures being performed in the United States is on the rise. American Society of Plastic Surgeons statistics indicate that 93,083 breast reconstruction procedures were performed in 2010; up from 86,424 in 2009.²

With the removal of the 1992 ban on silicone breast implants by the Food and Drug Administration in 2006, and technical advances in plastic surgery, a variety of breast reconstructive options are available to women who are considering breast reconstruction following mastectomy. The decision making process is complex, and the reconstructive options can be limited for some patients, depending on the recommended oncologic treatment. Also influencing the decision are the patients’ individual risk factors, such as obesity, a smoking history or other medical conditions that could impact the recovery from surgery. Finally, techniques in breast reconstruction surgery continue to change, making it difficult for the surgical team to determine the specific risks and benefits associated with the various surgical

approaches. All of these factors were considered by the QPS Division when determining the scope of the project.

The Expert Panel

The *Expert Panel to Review Immediate Implant-Based Breast Reconstruction following Mastectomy for Cancer* was convened under the auspices of the QPS Division and the Betsy Lehman Center. The Panel's goal was to review and analyze current scientific literature, identify those areas of practice where there is consensus and make recommendations that would encourage a consistent approach to the surgical care of breast cancer patients who are candidates for breast reconstruction following mastectomy. The specific focus of the Panel was on immediate implant-based breast reconstruction.

The Panel membership included patient representatives, and experts in the fields of breast surgical oncology, plastic surgery, radiation oncology, infectious diseases, epidemiology, medical oncology, nursing, and social work. Members also included hospital surgical department chairs, experts in quality and patient safety, surgical data collection experts and a representative from the Massachusetts Cancer Registry. An effort was made to select members who could represent the geographical areas in the state, as well as the hospitals performing both small and large volumes of these procedures.

The Panel was chaired by Margaret Duggan, MD, a specialist in surgical oncology at the Faulkner Hospital, and Bernard Lee, MD, a plastic surgeon specializing in breast reconstruction at the Beth Israel Deaconess Medical Center. The work of the Panel was supported by a project director, research coordinator and research librarian. The Panel convened its first meeting in June 2010. The Panel members were divided into five "task groups," with assigned leaders or co-leaders to do the work. Between June and January 2011, the Task Groups met independently, with periodic meetings of the full Panel membership to discuss the progress of the project.

The Task Groups approached their review with primary focus on 1) the processes utilized to assist patients in making informed decisions about breast reconstruction; and 2) the surgical care of patients who choose to have immediate, implant-based reconstruction. Each task group had a goal, with the following specific areas to consider during their review.

1. *Surgical Options Task Group (the "decision")*

Once the patient decides to undergo total mastectomy and breast reconstruction, what reconstructive options are available to her? What are the factors that will influence her decision?

Goal: Develop a tool to guide the patient and her medical team in making decisions for reconstructive surgery following mastectomy.

Factors to consider: tumor size and anticipated extent of mastectomy; body type and anatomical variations; medical history and general physical health; adjuvant therapy (e.g. radiation, chemotherapy); other risk factors, (e.g. obesity, smoking history); lifestyle; quality of life concerns; and personal preferences.

2. Implant-based Surgery Task Group (the “surgery”)

The patient decides to undergo mastectomy with immediate implant-based reconstruction. What are the current evidence-based standards for these procedures? Are there areas of consensus on particular techniques for doing these procedures?

Goal: Through evaluation of the scientific evidence governing implant-based reconstructive surgery and through consensus, make recommendations that would promote consistent evidence based surgical practices. In addition, make recommendations for further research in this area of practice.

Factors to consider: evaluation of the various types of implant-based procedures; surgical techniques to prevent complications; use of prosthetic materials; challenges associated with immediate reconstruction, which involves two procedures (mastectomy and reconstruction); training and mentoring; and credentialing and privileging criteria.

3. Perioperative Care Task Group (the “process”)

What is required to ensure that the patient has an optimal surgical outcome, without infection or other complications?

Goal: Develop a tool to guide the multidisciplinary team in the pre-operative and postoperative care of patients who undergo mastectomy with immediate implant-based reconstruction.

Factors to consider: preoperative care plan (e.g. pre-op screening for MRSA, skin prep, glucose control, antibiotic prophylaxis); postoperative care plan (e.g. drain care and dressing change protocols, medical management); length of stay; short term and long term out patient follow-up; response to evidence of infection or other complication (e.g. treatment of seroma, tissue necrosis, contracture, when to treat in office vs. hospital readmission); and coordination of patient management with the multidisciplinary team (plastic surgery, breast surgery, radiation oncology, medical oncology).

4. Patient Education Task Group (“empowering” the patient)

How can the patient be empowered so that she can (1) make an informed decision concerning her breast reconstruction options; and (2) be an active participant in the perioperative process?

Goal: Develop tools for health care providers to educate patients about implant-based reconstruction, risks associated with the procedures, prevention of complications, psycho/social issues, and other factors, so that patients can make informed decisions about their care. Develop guidelines for the informed consent process.

Factors to consider: Anticipate questions a patient may have when considering reconstructive surgery, such as: whether implant reconstruction is the correct choice for me; what are the risks given my diagnosis, cancer treatment plan, general health and medical history; how are implant-based reconstruction procedures performed; what products will be used for the procedures and what are the associated risks; what can I expect before, during and after surgery; what do I need to know when I go home after surgery to prevent complications; how will I look; how will I feel; and what about long term consequences and follow-up?

5. Outcomes Measurement Task Group (“continuous improvement”)

Is it possible to collect outcome data for implant-based reconstruction state-wide, in order to further study the procedures and continuously improve outcomes?

Goal: Develop methods for uniform collection of data on implant-based breast reconstruction. Make recommendations for a statewide-approach to data collection for these procedures, such as a registry.

Factors to consider: number of participating hospitals and volume of procedures; specific criteria for data collection; consistency in approach to data collection; available technology; resources.

Methodology

The Task Groups, with the assistance of the librarian and research coordinator, undertook a comprehensive review of the literature for their particular area of focus. With one exception, the literature was graded, using tools developed by the Centre for Evidence Based Medicine.³ (The recommendations made for surgical site infection prevention are based on the work of the *Massachusetts Healthcare Associated Infection (HAI) Prevention Expert Panel*. The HAI Panel developed a comprehensive grading methodology, described in detail in its report: *Prevention and Control of Healthcare-Associated Infections in Massachusetts. Part 1: Final Recommendations of the Expert Panel*.⁴)

Through their literature review, the Task Groups confirmed the QPS Division’s initial findings that there is limited research in this field and a need for comprehensive, prospective data collection and research to support the development of evidence-based guidelines for breast reconstruction surgery. The Task Groups were able to focus on the development of consensus statements and recommendations for patient education and informed consent; identification of and response to risk factors; surgical site infection prevention; and processes for privileging surgeons to perform these procedures in hospitals.

The Task Groups prepared draft reports of their findings, recommendations, and those areas of practice for which the literature could not support any definitive recommendations. The Task Group reports were then discussed at full Panel meetings, with the findings ultimately combined into this final report, which is divided into four parts. *Surgical Options* is a discussion of the risks and benefits of the various reconstructive options available to patients. *Patient Education and Informed Consent* identifies key elements of an effective, patient-centered decision making process for breast reconstruction. *Implant-Based Breast Reconstruction: Technical Considerations and Perioperative Care* focuses on patient selection for immediate implant-based reconstruction, surgical site infection prevention, and surgical privileging. *Improving Clinical Options: Collaborative Approach to Data Collection* reviews the evidence-based literature that supports the development of a uniform statewide data collection system.

Next Steps

This report is a culmination of the Panel’s work, accomplished over a period of twelve months. It discusses current practice in breast reconstruction and includes consensus statements and recommendations for patient education, perioperative care and further research. The goal of the Panel was to provide guidance to health care facilities and providers, but the Panel hopes that this report will also be useful to patients.

As of the date of publication of this report, the work of the Panel continues. An advisory committee will consider options for development of a state-wide data collection system. In addition, members of the Patient Education Task Group plan to develop educational materials for patients, based on the Panel's recommendations.

The Panel hopes that the guidance offered in this report, as well as the continued efforts to improve data collection processes and education, will support hospitals in their efforts to ensure that breast cancer patients are receiving evidence based, quality care.

II. EXPERT PANEL CONSENSUS STATEMENTS AND RECOMMENDATIONS

This summary provides a highlight of the Panel's consensus statements and recommendations. Supporting references and the process through which they were accomplished are contained in the following pages of this report.

Patient Education and Informed Consent

1. Providers should have a compassionate and patient-centered process for presentation of options and preference-sensitive decision-making. The key elements of this process should include (1) a recognition that the weeks immediately following a diagnosis of breast cancer are the most psychologically difficult phase of the patient's breast cancer experience; (2) allowance for a period of time to build trust and understand the patient's emotional well-being, values, knowledge and desire to participate in the decision-making process, (which can require additional access to the plastic surgical consultant beyond an initial consultation); and (3) an understanding that the patient's values and preferences must be considered when discussing the risks/benefits of the reconstructive options, including an option for "no" reconstruction.
2. Appropriate management of the patient's expectations for breast reconstruction is an important aspect of the process of decision-making and informed consent. Providers should engage in a respectful, compassionate and honest discussion with the patient about what to expect at each of the different postoperative stages, including the facts that reconstruction does not restore the original breast and the reconstructed breast will not look or feel the same as the original breast, even with an excellent surgical outcome.
3. Patients who take an active role in decisions about treatment in partnership with their health care providers are often more satisfied with the results of their treatment selection and the outcomes are more positive. Shared decision-making (SDM) is defined as the process by which treatment decisions are shared by doctors and patients, informed by the best evidence available and weighted according to the specific characteristics and values of the patient. SDM should be an essential component of the informed consent process for mastectomy and breast reconstruction.
4. Well written, clinically accurate decision aids are essential to support the informed consent and SDM process. The Panel recommends that women have access to multiple decision aids. This can include a multi-media tool-kit that combines printed information, video (or a DVD), and on-line resources. Such a package can give patients ideas about specific questions that can form the basis for discussions with her physician. Also, it allows a woman to learn the information at her own pace, at home, before she comes in to discuss with her doctor.
5. Informed consent is a process, not a one-time act of reviewing and signing a form. It is a process that is derived from the ethical and legal obligations of the treating provider toward the patient and includes the time it takes for a particular patient to become acclimated to her diagnosis. The process should cover the nature of the decision/procedure; the reasonable alternatives to the proposed intervention; the relevant risks, benefits, and uncertainties related to each alternative; an assessment of patient understanding; and an acceptance of the intervention by the patient.

Risk Factors, Technical Considerations and Perioperative Care

1. The primary consideration in determining whether a patient is a candidate for immediate breast reconstruction is whether the patient will require adjuvant radiotherapy. In those circumstances, it is recommended that breast reconstruction be delayed. In patients who may face difficulties with delayed reconstruction because of lack of donor site availability, a tissue expander and skin sparing mastectomy may be considered in order to preserve the patient's native skin envelope.
2. Five variables can contribute to complications associated with breast reconstruction: 1) smoking; 2) obesity; 3) radiation before, during or after the reconstructive effort; 4) ischemic or necrotic mastectomy flaps after breast reconstruction; and 5) neoadjuvant chemotherapy. In addition, implants, expanders and acellular dermal matrix, are medical devices and carry inherent risks. During the informed consent process, patients should be made aware of the increased risks associated with immediate implant-based breast reconstruction, and the discussion documented in accordance with informed consent protocols.
3. This report includes *Recommendations for Prevention of Surgical Site Infections following Mastectomy and Breast Reconstruction*, which are consistent with the recommendations of the Massachusetts Healthcare Associated Infection Expert Panel. For patients who develop evidence of infection, aggressive, early surgical intervention and more liberal use of explantation should be considered if there is no early response to antibiotic treatment.
4. Consistent with The Joint Commission standards, hospitals should develop a Focused Professional Practice Evaluation (FPPE) for surgeons who desire to perform breast reconstruction procedures, to ensure competence and documentation of appropriate training. The FPPE should include procedures for observation by another surgeon experienced in breast reconstruction techniques and tracking of outcomes.

Improving Clinical Outcomes: Collaborative Approach to Data Collection

1. Collection of clinical data is critical to continually monitor breast reconstruction outcomes and assess efficacy of the treatment. The need for a comprehensive data collection system is supported by: 1) the growing consumer demand for breast reconstruction; 2) the clinical variables associated with the overall oncologic treatment; 3) the reliance in implant-based reconstruction on medical devices, which are continually changing; and 4) the need for scientifically based data upon which patients can rely to make informed decisions.
2. Through the collaboration of the hospitals in Massachusetts that perform breast reconstruction, the first steps can be made toward the development of a data collection system that meets best practice standards for data collection. Currently, the Massachusetts hospitals that are members in the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) are considering participation in the NSQIP targeted program for breast reconstruction, with a goal to collaborate and share lessons learned from the NSQIP analysis of outcomes.

III. SURGICAL OPTIONS IN BREAST RECONSTRUCTION

Recent advances in prosthetic and biologic implants, combined with improvements in reconstructive flap procedures, have expanded surgical options for women who chose breast reconstruction following mastectomy. Each approach presents unique advantages and shortcomings. Improving quality, by decreasing complications and proper patient selection, is important as it has been shown to be associated with higher patient satisfaction.

The overriding goal of reconstructive breast surgery is to perform a safe operation that can restore self-image. Although reconstructive in nature, breast reconstruction is accomplished based on aesthetic principles. There are a number of variables that must be considered when selecting the appropriate operation. Patient-related factors include breast size, breast shape, body mass index (BMI), smoking status, prior surgeries, expectations and desires. Oncologic factors include tumor size, nodal status and prior history of radiation treatment or its necessity after mastectomy. Surgeon-related factors may also be important in the decision making process, such as the technical ability of the surgeon to offer a variety of procedures in a predictably safe and effective manner.

Although breast reconstruction following mastectomy is widely practiced, this Panel recognizes that patients should be offered the option of having no reconstruction. Breast reconstruction following mastectomy provides the physical benefit of not having to wear an external prosthesis and can ease the negative impact on a patient's body image. However, some women view their choice of no reconstruction as positive and feel very comfortable with their bodies and their decision.

Timing of Breast Reconstruction

In appropriately selected patients, reconstruction performed concurrently with mastectomy is an oncologically safe procedure.⁵⁻⁹ Immediate reconstruction with a skin sparing mastectomy preserves the breast skin envelope, except the nipple areola complex, and results in a superior aesthetic outcome compared to delayed reconstruction. Immediate reconstruction allows the plastic surgeon to work with a pliable native skin envelope, well-defined inframammary fold, and lateral breast border. There is the added potential advantage of fewer surgical procedures and a quicker return to normal life. Immediate reconstruction should be considered for any patient who is interested in breast reconstruction, and who presents for either prophylactic mastectomy or with a clinical cancer stage that will not usually require post mastectomy radiation treatment (Stage 0, stage I and clinical stage II, T1-2 and N0).

Current evidence shows that the need for chemotherapy, whether prior to or after mastectomy does not directly impact the long term outcome of reconstruction. Adjuvant radiotherapy, however, increases the risk of postoperative complications following immediate reconstruction procedures.^{8,10-15} These complications can result in poor cosmesis from the negative effect of radiation on skin pliability and the distortion of the skin envelope. It is generally recommended that reconstruction be delayed in cases when postmastectomy radiation treatment is required, such as for patients with clinical stage II node positive, and stage III breast cancer.^{5,10,11,16} If the patient desires immediate reconstruction under those circumstances, the increased risk of complications associated with post-reconstruction radiation needs to be discussed at length, to ensure the patient's understanding; and the discussion documented in accordance with informed consent protocols.

The clinically node negative patient desiring immediate post mastectomy reconstruction, routinely undergoes a synchronous intraoperative sentinel node biopsy. Even with a reassuring negative axilla by palpation and imaging (ultrasound, MRI, or PET), the patient has a ten to twenty percent (10-20%) risk of a positive sentinel node biopsy. This can result in a decision for post mastectomy radiation therapy. Whether there will be an intraoperative decision made to abort reconstruction in this situation is an important question for discussion between the patient and the multidisciplinary team prior to the planned mastectomy.

Breast reconstruction is not considered the standard of care for patients with metastatic breast cancer, as the increased morbidity and recovery following breast reconstruction may interfere with critical systemic therapies.^{8,17} Patients with advanced disease or unknown prognosis may be better served with delayed or no reconstruction.

Some patients are unable to decide about primary reconstruction while adjusting to their breast cancer diagnosis. They may desire to wait until all cancer treatment is complete before making a decision for reconstruction. In those cases, the option of delayed reconstruction should always be offered.

Types of Breast Reconstruction

Breast reconstruction can be achieved using either prosthetic devices or autologous tissue flaps, or a combination of these two approaches. American Society of Plastic Surgeons statistics demonstrate that over 75 percent of women across the United States will have prosthetic reconstruction compared with 25 percent who will have autologous reconstruction.¹⁸ This statistic is influenced to some degree by surgeon preference and regional differences. This potential bias should be discussed with the patient.

Implant-based reconstruction

Implant-based reconstruction has the distinct advantage of being a less invasive procedure with easier recovery as there is no distant donor site morbidity. Although the overall risk of complications may be low in properly selected patients, implants are foreign materials and carry risks of infection that may lead to prosthetic removal. Other risks associated with implants include capsular contracture, leakage, malposition, and extrusion which all may require additional surgery and implant replacement.

The ideal candidate for implant-based reconstruction is a patient with low BMI, small to moderate breast volume, and mild to moderate ptosis. Patients with an active life style, who do not accept the risk of donor site morbidity of a major autologous flap, may prefer this type of approach. Similarly, patients who desire future pregnancy may potentially choose an implant-based reconstruction, rather than autologous reconstruction with an abdominal flap.

Patients who choose to undergo a prophylactic contralateral mastectomy at the time of their therapeutic mastectomy may be good candidates for prosthetic reconstruction, as a symmetric bilateral implant reconstruction is easier to achieve. Patients with large breast volume and significant ptosis, may likely require a matching procedure of the opposite breast.

Prosthetic breast reconstruction can be accomplished in one stage, using a permanent implant, usually in conjunction with acellular dermal matrix. However, in the majority of cases a far more

reliable approach involves two-stage (tissue expander to implant) reconstruction.^{8,9,19,20} This technique requires placement of a temporary tissue expander at the time of immediate breast reconstruction or in the first stage of delayed reconstruction. It is used particularly when there is insufficient tissue after mastectomy, or more commonly, when the desired size and shape of the breast cannot be safely or predictably achieved in a single stage procedure. Potential stress placed on the mastectomy skin flaps by a fully filled saline implant or silicone implant introduced in one stage is also avoided by this staged procedure design.

Lack of adequate breast skin envelope to cover an implant is considered a contraindication for prosthetic breast reconstruction. This may be the case when a large skin excision is performed because of previous biopsies and/or locally advanced disease, precluding the primary coverage of the implant. In such cases, autologous reconstruction may be indicated.

Autologous tissue reconstruction

While the implant-based reconstructive techniques may lead to a flat contour or asymmetric appearance of the reconstructed breast, breast reconstruction with autologous tissue flaps can generally achieve more natural-appearing results. This type of approach also results in a more durable outcome compared with prosthetic reconstructions, which may deteriorate over time due to capsular contracture. Results can be long lasting with less need for revision after weight gain or loss. Furthermore, there may be less need to modify the opposite breast because the autologous tissues are often versatile in size and shape, allowing the surgeon to create a breast mound that can better match the contralateral breast.

Any patient with excess skin and fat in an autologous tissue flap donor site is a candidate for this approach. The best candidate is a patient with larger volume ptotic breast, moderate BMI, and who is able to tolerate potential donor site morbidity. However, autologous tissue breast reconstruction can be successfully performed with good outcomes in a wide variety of breast volumes and also in bilateral reconstruction.²¹⁻²³

In general, autologous tissue breast reconstruction is a longer operation with longer recovery than prosthetic reconstruction. This procedure carries specific risks, including scarring, contour deformity, and donor site morbidity (weakness or hernia) depending on the type of flap chosen. In the case of breast reconstruction requiring microsurgical tissue transfer, there is the inherent risk of complete flap loss, although this is a small risk in experienced hands.

The lower abdomen is the most commonly utilized donor site for autologous tissue breast reconstruction, allowing for improvements in abdominal contour similar to abdominoplasty. There is no standard in choosing the type of abdominal flap, as each option has advantages, disadvantages, and risks. The traditional pedicled TRAM flap, using abdominal tissue, is the most common method of reconstruction in the United States. With a pedicled TRAM flap, the rectus muscle is transferred with the skin and fat to create a new breast construct. Notable complications include partial flap necrosis, fat necrosis, and donor site morbidity such as abdominal weakness or hernia. Microsurgical transfer of abdominal tissue as a free flap may diminish some of the shortcomings of the pedicled TRAM flap, however at the cost of more technically demanding procedure and a risk of complete flap loss. These options include free TRAM flap, muscle-sparing free TRAM flap, DIEP flap, and SIEA flap. As the muscle component of the flap transferred is diminished or eliminated, such as in SIEA or DIEP or muscle sparing TRAM flap options, there may be fewer abdominal donor site complications.

In patients where the abdomen is not a suitable donor site, autologous breast reconstruction can be considered from alternate donor sites. These include gluteal flaps, Rubens flap, and inner thigh flaps. A detailed discussion with the patient is essential prior to choosing any of these less commonly performed flaps as the level of technical difficulty is increased. In such situations, it may be desirable to refer the patient to tertiary care centers with particular expertise.

Combined implant and autologous reconstruction

Prosthetic breast reconstruction can be combined with an autologous tissue flap allowing for coverage of a tissue expander or implant. The most common option in this scenario is the latissimus muscle flap. Advantages of this approach include improved breast mound projection, as well as a decreased contracture rate. A single stage reconstruction with latissimus flap and a permanent implant is a common reconstructive choice.

A previous history of irradiation is considered by many a contraindication for implant-only breast reconstruction.^{14,24,25} Autologous tissue may be preferred in such cases. Alternatively, in women interested in prosthetic reconstruction, a latissimus flap can be combined with implants, either in an immediate or delayed reconstruction setting. This approach can provide the needed skin coverage in patients treated with post mastectomy radiation while decreasing the complication rate.

Conclusion - Surgical Options

Refinements in autologous flap techniques, improvements in prosthetic technologies and the development of novel tissue substitutes have allowed for continued improvements in breast reconstruction outcomes. In the future we can also expect that many new options and techniques will have a substantial impact on reconstructive breast surgery, including nipple sparing mastectomy, oncoplastic surgery, new biologic tissue matrices, different forms of radiation therapy, neoadjuvant chemotherapy, long term hormonal treatment, and the use of angiogenesis inhibitors.

There is no right approach that can be adopted as the standard; rather, the decision should be individualized depending on patient-related and oncological factors. Autologous tissue reconstruction may be preferred based on relative permanency of its results and elimination of dependency on a permanent prosthesis; whereas a prosthetic reconstruction may be favored as a less invasive procedure that is generally well tolerated. Irrespective of the technique chosen, the main goal of breast reconstruction is to improve patient satisfaction, self-image and expectations, while minimizing morbidity.

IV. PATIENT EDUCATION AND INFORMED CONSENT

The weeks immediately following a diagnosis of breast cancer are highly stressful. Most women retrospectively identify this period of medical appointments and treatment decisions as the most psychologically difficult phase of their breast cancer experience. Women are flooded with information at a time when due to anxiety appropriate to the situation, they cannot carefully consider and process the conversations as well as they might otherwise. Learning the language of medicine and science, meeting several physicians, and trying to navigate complex institutions and systems, patients often are overwhelmed and frightened. Women who are medically sophisticated may have the opposite problem of knowing too much as they try to make the best decisions regarding surgery. (Hester Hill-Schnipper, personal communication)

Because this stress can limit individuals' ability to absorb and process information, a coordinated process should exist to provide a continuum of education and information. Such a process would provide patients and their families with support during this difficult time and with an organized way to proceed with their decision-making in collaboration with their physicians in a compassionate, patient-centered way that is sensitive to the patient's preferences.

The key elements of such a process include: 1) recognition that the weeks immediately following a diagnosis of breast cancer are the most psychologically difficult phase of a patient's breast cancer experience; 2) allowance for a period of time (usually more than one meeting) to build trust and understand the patient's emotional wellbeing, values, knowledge, and desire to participate in the decision-making process; and 3) understanding that a patient's values and preferences must be considered when discussing the risks/benefits of various reconstructive options, including no reconstruction.

There are few studies examining specifically how women make decisions about having reconstruction, what kinds of information they feel are most important in making this decision or deciding what type of reconstruction to have, or whether they find decision aids (e.g., pamphlets, audio or video recordings, or computer-based interactive programs) useful. The studies do, however, provide some evidence to suggest guidelines for physicians to use in helping women make the decisions that are best aligned with women's individual preferences and needs.

Interactions between Providers and Patients

Informed consent is a process that is derived from the ethical and legal obligations of the treating provider to the patient, not a patient's one-time act of reviewing and signing a form. This process includes the provider's need to give whatever time is necessary for a particular patient to become acclimated to her diagnosis. The process should cover, among other issues, the nature of the decision and procedures; the reasonable alternatives to the proposed intervention; the relevant risks, benefits, and uncertainties related to each alternative; an assessment of patient understanding; and an acceptance of the intervention by the patient.

Patients generally consider physicians to be the best source of information about surgical decisions.²⁶ The influence of the breast surgeon on patients' decision-making is critical. One study found that patients, who before having any surgery heard about reconstruction from the breast surgeon were four times more likely than patients who did not have such a discussion to choose mastectomy over breast-conserving surgery.²⁷ Thus, it is important that each of the

patient's providers (not just the plastic surgeon) give consistent information on these issues, and that each provider have the same knowledge of that patient's specific needs and preferences. Failure to discuss reconstructive options with a patient soon after diagnosis can greatly influence her decision-making.

The relationship a patient has with the plastic surgeon is critical to the patient's ability to make the best decision. In one study, patients who were asked to rank-order 100 potential factors affecting their decision-making regarding reconstructive surgery placed experiencing a sense of trust, support, and kindness from the plastic surgeon at the top of their list.²⁸ Therefore, breast surgeons ideally will provide women with a choice of plastic surgeons to interview to decide which doctor meets her preferences and needs.

Patients who partner with their health care providers in decisions about treatment are often more satisfied with their treatment experiences and outcomes.²⁹⁻³¹ Such shared decision-making (SDM) is defined as the process by which treatment decisions are: shared by doctors and patients; informed by the best evidence available; and weighted according to the specific characteristics and values of the patient. SDM should be an essential component of the informed consent process for mastectomy and breast reconstruction.

Each woman facing breast cancer needs compassionate caregivers who will take the time to get to know her, to understand her knowledge of treatment options and her desire to obtain information, and to learn the degree to which she wants to participate in decision-making. Because the patient's ability to absorb new information may be limited by the stress and anxiety of the situation, compassionate caregivers also will give the patient however much time she needs to process the information and make an informed decision. This commonly requires prolonged discussion about options, procedures, risks, and potential outcomes, which can require additional access to the plastic surgical consult beyond an initial consultation. Some of this discussion can be delegated to experienced nurses or individuals with advanced-practice credentials who work closely with the plastic surgeon.

Information Patients Want to Know and Should Know about Reconstruction

While the focus of this report is the use of implant-based reconstruction immediately after mastectomy, a plastic surgeon must discuss all reasonable alternatives with a patient to enable the patient to make an informed decision and give truly informed consent. Unfortunately, there are few high-quality instruments for measuring women's assessment of the outcome of reconstructive surgery, and the studies in this area are generally substantially flawed.³²⁻³⁴ In particular, though several studies suggest that patients undergoing different reconstructive procedures have roughly similar degrees of satisfaction,^{24,35} this area needs more research, particularly for specific patient subgroups (e.g., those undergoing radiation therapy). Also, at least one study found that patients' views of the results of reconstructive surgery change over time.³⁵ Hence, practitioners need to be very cautious in comparing patients' long-term satisfaction with different reconstructive approaches or with immediate reconstruction compared to no reconstruction after mastectomy.

Few studies have attempted to examine the views of women and their providers concerning what information is critical to the decision about reconstructive surgery.^{28,36} There are sometimes substantial differences between what each sees as most important. For example, in one study patients and providers most frequently selected the same two top goals of

reconstructive surgery: to minimize the number of operations and to look natural in clothes (Table 1).³⁶ However, patients placed greater importance on avoiding a prosthesis than providers did (33% versus 0%) and were less concerned about looking natural without clothes (24% versus 40%).

Therefore, first and foremost, caregivers must discuss with a patient her preferences and values. What considerations are most important to the patient concerning her diagnosis and her treatment? What kind of lifestyle does she lead? What does she care about most in terms of physical appearance? What kind of cosmetic result matters most to her? What kind of recovery time from surgery can she manage and does she want given her lifestyle, family situation, and commitments?

After the patient's preferences have been established, a caregiver needs to present the risks and benefits associated with the options for reconstruction such that the patient thoroughly understands this important information. The practitioner is responsible for ensuring that the patient understands the reconstructive options and their risks and benefits, including realistic expectations for its outcomes. Broadly these topics include: what is known and not known about results using alternative procedures in the context of the overall treatment program, including the possible use of chemotherapy and radiation therapy; and the standard as well as less common short- and long-term cosmetic outcomes and complications. Providers should engage in a respectful, compassionate, and honest discussion with the patient that reconstruction does not restore the original breast and that even with an excellent surgical outcome, the reconstructed breast will not look or feel the same as the original breast did. The discussion must include the need for additional surgeries to complete the reconstructive process. Practitioners also must provide clear information about pre-operative and post-operative care and recovery.

Tools and Resources for Improving Understanding and Decision-Making

While the law mandates that informed consent forms must be read and signed by the patient prior to any procedure, the forms should not be the only medium used to educate the patient. Informed consent is a process, not a one-time act of reviewing and signing forms. Many hospital breast centers and individual plastic surgeons distribute pamphlets listing the advantages and disadvantages of reconstructive procedures. The value of this type of written material has not been studied specifically for patients contemplating reconstructive surgery. However, studies in other areas of medicine suggest that such materials has, at best, modest benefits.^{37,38}

There are many online sources of information about breast reconstruction including the websites of the American Society of Plastic Surgeons, BreastCancer.org, and Oncolink. However, there are no studies of how useful such sites are to patients trying to make decisions regarding reconstructive surgery. The Panel found that while some of these sites provided useful introductory material, overall the sites had limited value for women trying to balance the complex clinical and personal needs required to decide about reconstruction.

Aids that more actively engage patients in the decision-making process may hold more promise.^{30, 39-41} There has been only one randomized trial examining the impact of such tools specifically concerning decisions regarding reconstructive surgery.⁴² Patients seen at the M.D. Anderson Cancer Center in Houston from 2003-2004 received either the "standard" printed material and information during consultations with medical professionals, or the standard

material plus an interactive digital education aid (on computer disc) including high-quality, three-dimensional animated graphics, patient testimonials, before-and-after photographs, and video explanations from plastic surgeons and clinical specialists in surgical, medical, and radiation oncology. Groups using the digital aid reported modestly higher overall satisfaction with the information medium they received than did the group given only the standard material (97% versus 86%, $p=0.03$). Patients in the former group also reported that they had received all the necessary information more often than did patients in the control group (95% versus 88%), that they were able to “easily” make a decision (97% versus 91%), that their reconstruction outcome met their expectations (95% versus 88%), and that they were pleased with their treatment choices (95% versus 83%, $p=0.03$). Use of the digital aid also modestly increased patients’ factual knowledge about reconstruction. However, there was no difference in patients’ scoring of how satisfied they were with breast reconstruction, and both groups reported an equal decrease in anxiety over time. Unfortunately, the study did not report how the intervention affected patients’ choice of reconstruction, and only half the patients who initially agreed to participate actually entered or completed the study. In a nonrandomized study performed at Beth Israel Deaconess Medical Center in Boston, the use of a module of written and visual information given to patients on computer disc improved patient satisfaction about the amount of information patients received from the reconstructive surgeon, and that information increased patient involvement in choosing their form of reconstruction.⁴³

These studies suggest that interactive digital education aids may modestly increase knowledge and satisfaction for women deciding about breast reconstruction. Well-written, clinically accurate decision aids are valuable in supporting the informed consent and SDM process. The Panel recommends that patients receive multi-media tool kits that combine printed information, video (or a DVD), and online resources at the beginning of provider-patient discussion about options. Such a package can help patients understand and articulate their questions and can provide a platform for important discussions with the physician. Also, material given in this multi-media form allows a woman to learn the information at her own pace and at home before she talks with her doctor. An outstanding example of comprehensive education and support material is “Breast Reconstruction: Is it right for you?” which combines a detailed, accurate booklet, a guide to online resources, and a 55-minute DVD in which patients and practitioners articulate the options and their decisions about reconstruction. This resource is available to practitioners from the Foundation for Informed Medical Decision Making.⁴⁴

Conclusion - Patient Education and Informed Consent

Much more research is needed to examine what aspects of breast reconstruction are most important to women, how best to structure the decision-making process, and the optimal means of providing patients the information they need. Nonetheless, it is clear that physicians must recognize that patients’ stress and shock about their diagnoses and the steps the patients are facing may compromise their full understanding of all the issues and options discussed in a single session with their provider. Additionally, some women may benefit from referral to an oncology social worker or other psycho-oncology therapist, who can help patients process their experiences and feelings. With or without such help, women will likely be more satisfied with their decisions if given multiple opportunities to learn about the risks and benefits of reconstructive surgery options. This may require several appointments with a plastic surgeon (rather than a single very long and detailed appointment), who can review important information more than once, answer questions, provide written or audiovisual materials and have an opportunity to discuss that material later, and offer to connect women with other

patients who have had similar surgeries. Busy practitioners may find it difficult to spend the extra time and effort that patients need to make the best decisions for themselves. However, investing that time will likely result in increased patient satisfaction with the process and outcome. That increased satisfaction and understanding ultimately will reduce practitioners' time post-surgery dealing with patients' emotional turmoil from disappointing outcomes or complications the patients did not understand or expect when they felt rushed into making a decision.

TABLE 1

Percentages of Patients and Providers Who Ranked Each Fact or Goal Among The Three Most Important Items to Know about Breast Reconstruction

	Patient (n=21)	Provider (n=20)
Reconstruction Fact:		
Radiation can increase complications and affect cosmetic result of reconstruction	24	60
About one-third will have a major complication in the 2 years after reconstruction	67	56
Reconstruction often requires multiple procedures over multiple visits to (n=21) complete	33	35
Reconstruction can be at the time of mastectomy or delayed for months or years	43	35
Women who do not have reconstruction generally as satisfied as women who do	5	30
Women who have flap are more satisfied with the look and feel than women who have implant	29	30
Immediate reconstruction offers more natural look and feel than delayed reconstruction	38	30
Implants require less extensive surgery than flaps	5	10
Women who delay reconstruction are as satisfied as women who have immediate reconstruction	24	5
Prosthesis can provide a 'natural look' in clothes	10	5
The data available to provide estimates of complications for reconstruction is limited	23	5
Reconstruction Goal:		
Look natural in clothes	43	60
Minimize the number of surgeries	71	60
Minimize recovery time	19	45
Look natural without clothes	23	40
Avoid a lengthy process	38	30
Use your own tissue to create a breast	43	30
Do what your doctor(s) think is best	24	15
Do what your spouse thinks is best	5	10
Avoid using a prosthesis	33	0

Adapted from: Lee CN, Dominik R, Levin CA, et al: Development of instruments to measure the quality of breast cancer treatment decisions. Health Expect 13:258-72, 2010

V. IMPLANT-BASED BREAST RECONSTRUCTION: TECHNICAL CONSIDERATIONS AND PERIOPERATIVE CARE

There are a wide variety of approaches to implant-based breast reconstruction after mastectomy. These include single stage reconstruction (direct to implant), two stage reconstruction (tissue expander to implant), the use of permanent expander combination implants, and finally the use of acellular dermal matrix broadly applied to the implant procedure. Patient selection, pre and post operative evaluation and management, and the quality of the surgical execution of the mastectomy and reconstruction will directly affect the success of the procedure.

Due to the lack of quantitative empirical data, the Panel found it difficult to make absolute recommendations to promote consistent practice in the area of implant-based breast reconstruction. The twelve plastic surgeons who participated on the Panel were selected to participate because they have extensive experience in performing implant-based reconstruction. They were polled via survey as to surgical preferences, in order to determine where common practice exists. In addition to the discussion and recommendations below, this report includes *Technical Considerations in Implant-based Reconstruction*, a review of the Panel member responses to the survey as well a consideration of general principles of surgical practice for implant-based breast reconstruction (*Appendix A*).

Risk Factors and Immediate Implant-based Breast Reconstruction

Review of the presently available literature offers little to direct decision-making regarding the choice of the reconstructive procedure for a particular patient. In the published literature, complication rates following immediate reconstruction vary between 1% and 50%, depending on the vast clinical differences between patients.^{11,45-47} Five variables can be identified that may contribute to complications associated with any given technique. They include: 1) smoking; 2) obesity; 3) radiation before, during or after the reconstructive effort; 4) ischemic or necrotic mastectomy flaps after breast resection; and 5) neoadjuvant chemotherapy.^{46,48,49} In addition, acellular dermal matrix, expanders and implants used in implant-based breast reconstruction procedures are medical devices and carry inherent risks. The literature suggests that there may be a higher rate of complications with regard to seroma or infectious complications when acellular dermal matrix is used in reconstruction,^{50,51} although acellular dermal matrix as an independent causative factor is the subject of much speculation and ongoing outcome research.^{6,52-54} Saline and silicone implants have recently been the subject of a Food and Drug Administration (FDA) Safety Alert concerning a possible association between the implants and anaplastic large cell lymphoma (ALCL).⁵⁵

Surgical judgment in the setting of immediate implant-based breast reconstruction is of paramount significance. Ultimately, it is the plastic surgeon's responsibility to assess all of the variables. In consultation with the patient and other members of the multidisciplinary team, the plastic surgeon should develop a surgical plan consistent both with desires of the patient and the demonstrable risks of the procedure. It is only through full and responsible discussion with the patient that these difficult and nuanced differences can be communicated. During the informed consent process, patients must be made aware that an attempt at immediate implant-based reconstruction carries with it substantially increased risks of complications. Such a discussion should be documented in accordance with informed consent protocols.

Ultimately, the decision to move forward with immediate reconstruction must be confirmed or ruled out in the operating room, at the time of completion of the mastectomy. Responsible surgeons acknowledge that an intraoperative decision by the plastic surgeon is a part of the process, and that a summation of factors at that point in time will in large measure set the stage for success or failure of the reconstructive procedure.

Throughout the preoperative and perioperative process, careful coordination and collaboration with the patient, her surgical oncologist and plastic surgeon, medical oncologist and radiation therapist will facilitate a surgical outcome that is optimal and satisfactory to the patient.

Prophylaxis and Perioperative Management

Other than immediate skin necrosis or hematomas, infections (early or late) represent the greatest challenges seen in implant-based breast reconstruction. Surgeons have had varying success reducing this complication. Implant loss is most likely related to some form of infection.^{46,56} This report includes *Recommendations for Prevention of Surgical Site Infections Following Mastectomy and Breast Reconstruction*, and represents the most up to date information for prevention of perioperative infection. (*Appendix B*) These recommendations for prophylaxis and perioperative management are consistent with the recommendations made by the Massachusetts Healthcare-Associated Infection Expert Panel.⁴

Acellular Dermal Matrix Protocols

The variety of forms of acellular dermal matrix, the multiplicity of vendors, and the inconsistent and proprietary nature of the material preparation, render it a complicated variable to assess. Vendors have differing recommendations for acellular dermal matrix preparation, creating some confusion about its handling. The surgeon should use cautious and careful handling when undertaking use of acellular dermal matrix. Thorough washing of this material in sterile saline baths should be considered. There is no data on the benefits of any particular protocol for preparing the acellular dermal matrix noted in the literature at this time.

Drain care, Dressing Changes, Medical Management

The management of hematomas is generally straightforward and is usually operative.^{57,58} The management of seromas and tissue expanders is more complicated but usually the routine and liberal use of drains is encouraged.^{48, 58-60} The presence of acellular dermal matrix does seem to influence the possibility of prolonged seroma formation.^{53,54} The use of drains when using acellular dermal matrix is indicated.

The literature supports a recommendation that drains not be removed until there is less than 40 cc drainage in 24 hours.⁶¹⁻⁶⁴ In common practice, most surgeons would support waiting until the drainage is less than 25 to 30 cc in 24 hours.

Length of Stay and Office Follow-up

In current practice most patients receiving implant-based reconstructions following mastectomy are routinely staying overnight in the hospital for 23 hours. There is no data to support any specific recommendation for length of hospitalization; nor are there recommendations for short or long term postoperative follow-up. Close serial evaluations of patients for complications such as skin necrosis, hematoma and infections should be performed with particular vigilance and frequency.

Response to Evidence of Infection.

The management of early or late infections in patients who undergo immediate implant-based reconstruction is the subject of much controversy.^{52,56,65} The development of erythema or cellulitis presages significant risks of eventual implant loss, and vigilance is necessary, particularly when acellular dermal matrix was used in the reconstruction. Factors to consider are the evaluation of the patient for fever, leukocytosis and systemic response, with cognizance that there is variability in the manner in which the patient may present, (i.e. a patient may have elevated WBC, but no fever). Consideration should be given to investigations, such as ultrasound to assess possible fluid accumulation.

Though controversial, there is Level 2 data to support management of early cellulitis without removal of the expander or implant.⁵⁶ While salvage is promoted as an option, its success may depend on many factors, such as the aggressiveness of antibiotic treatment. Aggressive, early intervention and more liberal use of explantation should be considered if there is no early response to antibiotic treatment.

Privileging of Breast Reconstruction

Ensuring the successful outcome of an implant-based breast reconstruction is ultimately the responsibility of the reconstructive surgeon performing the procedure. This statement respects and acknowledges that there are many other factors not under the surgeon's control that have substantive impact on the outcome. Only through a process of careful evaluation and preparation before surgery, thoughtful and skillful execution of the surgical procedure, with clear intraoperative judgment regarding appropriateness to proceed, and meticulous post-operative care can the complications associated with this surgery be kept to acceptable levels.

The techniques of basic breast reconstruction after mastectomy are part of Plastic and Reconstructive Surgery residency programs. However, technical proficiency and surgical judgment vary among clinicians and there is a learning curve for acquisition of new skills, even after completion of a plastic surgery training program. Newer and more advanced breast reconstruction techniques are not routinely taught as a part of the typical plastic surgery training program. The judgment required to decide which patients are candidates for the various breast reconstruction procedures is similarly much harder to learn.

The Joint Commission has developed a mechanism for ensuring that physicians are appropriately skilled in the management of the specific diseases they treat and the procedures they perform.⁶⁶ A Focused Practitioner Performance Evaluation (FPPE) must be completed within a few months of a new physician's appointment to the medical staff, or within several months of an established physician beginning to perform a new procedure. The Panel makes the following recommendations for development of an FPPE for surgeons performing breast reconstruction. While the scope of this Panel's review was primarily on implant-based reconstruction, these privileging recommendations are applicable to surgeons performing autologous reconstruction, as well.

For all newly appointed surgeons, who will be performing breast reconstruction surgery, the Panel recommends that the FPPE include: 1) a comprehensive evaluation of the surgeon's management of breast cancer patients; 2) documentation of appropriate training; 3) observation(s) by another surgeon experienced in breast reconstruction techniques; and 4) tracking of outcomes.

When a new or established surgeon wishes to become privileged to perform an advanced breast reconstruction technique new to their institution or to their personal repertoire, the FPPE performed to ensure competence with that new technique should include documentation of appropriate training stating: 1) the volume of experience under the guidance of a proctor; 2) that proficiency in both case selection and surgical technique has been achieved; 3) demonstration of an understanding of appropriate case selection, the technical aspects of the procedure and the management of potential complications; 4) observation(s) by another surgeon experienced in the new technique; and 5) tracking of outcomes. In those situations where an experienced surgeon is not available for direct observation during the FPPE process, pre-operative review of the first several cases with an experienced surgeon is acceptable.

Conclusion - Technical Considerations and Perioperative Care

While the Panel found it difficult to make absolute recommendations for consistent practice, the members unanimously agreed that the following factors are crucial to achieving a positive outcome for the patient: 1) careful preoperative risk assessment; 2) collaboration between the surgical and medical team; 3) honest discussion with the patient about risk factors; 4) a willingness to make an intraoperative decision about whether to proceed with reconstructive surgery; 5) meticulous surgical site infection prevention techniques; and 6) vigilant attention to signs of infection during postoperative period. Finally, by having robust medical staff credentialing procedures hospitals can ensure that surgeons have the skill and judgment that is required for appropriate patient selection, surgical technique and postoperative management.

VI. IMPROVING CLINICAL OUTCOMES: COLLABORATIVE APPROACH TO DATA COLLECTION

There are only a few databases identified for the sole purpose of reviewing post-mastectomy breast reconstruction surgery. The major studies include the Danish Breast Cancer Cooperative Group (DBCG)⁶⁷ and UK National Health Service Breast Cancer – Collaborative Initiative.⁶⁸ The Panel broadened its search to include surgical databases and registries that have been tested by time. They include: American College of Surgeons National Surgical Quality Improvement Project (NSQIP), Bariatric Databases; Total Joint Registries; and The Society of Thoracic Surgeons (STS) National Database. The Panel's recommendations are based on available evidence as well as consensus of opinions from its members.

No previous research has been performed to assess whether data collection on implant-based breast reconstruction improves clinical outcome and patient safety. However, available literature from other surgical specialties has shown that regional collaboration and National Programs, such as the Danish Breast Cancer Cooperative Group, NSQIP, and the STS National Database have been used to significantly reduce post-operative adverse events.⁶⁷⁻⁷⁰

There is no standardized data collection system established for breast reconstruction data. Several academic medical centers are currently collecting breast reconstruction data independently; however, there are no standard definitions or validation process for these databases. Currently only cardiac and bariatric surgery specialties collect data in a systematic approach through their respective professional organizations.⁷¹⁻⁷⁴ The Joint Commission and the Centers for Medicare and Medicaid Services require accredited hospitals to collect and submit performance data so that they can review clinical trends that have a significant effect on patient outcomes.⁷⁵ Currently, the American College of Surgeons is in the early process of formulating a Breast Reconstruction Module using the NSQIP Program.

Implant-based breast reconstruction modality is the most common method of breast reconstruction after mastectomy, and the technique continues to evolve over time to achieve better reconstructive outcome. While it provides the least invasive reconstructive option without donor-site morbidity, potential surgical complications such as infection can be devastating and can lead to ultimate reconstructive failure. Collection of clinical data is critical to continually monitor outcomes and to assess efficacy of the treatment. A number of other considerations support the need for a comprehensive data collection system: 1) the growing consumer demand for breast cancer reconstruction;⁷⁶ 2) the clinical variables associated with the overall oncologic treatment (i.e. mastectomy technique, chemotherapy, radiation, and prior oncologic treatment) can significantly impact the reconstructive outcome; 3) implant-based breast reconstruction relies on the use of devices and products, which are continually changing, such as breast implant choices and acellular dermal matrix options; and 4) the need for scientifically based data upon which patients can rely to make informed decisions.

The Panel recommends the establishment of a committee, whose mission will be to explore options for the development of a state wide data collection system for all programs and medical centers that perform breast reconstruction. This would allow for careful evaluation of current clinical practices to identify areas which need further research and to develop an evidence-based guideline to optimize clinical outcomes in treating breast cancer patients. The proposed system should adopt best data collection practices: confidential; prospective and retrospective;

risk –adjusted; multicenter; data validation; common definitions; trained abstractors; automate data collection; and oversight from an objective respected organization.

One potential way to accomplish the Panel’s goal would be to utilize the NSQIP breast reconstruction module which is in its early stage of development. This program would allow the participating hospitals to collect 100% of breast reconstruction procedures and collect up to 25 data elements relevant to patient outcomes.

Conclusion - Improving Clinical Outcomes

At this report's publication date, the Panel has established a committee to continue the Panel’s work. Ongoing data collection will allow for the establishment of a breast reconstruction database to track representative outcomes for the state of Massachusetts with the ultimate goal of improving patient safety.

REFERENCES

1. American Cancer Society. Cancer Facts & Figures, 2010. Available at <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-026238.pdf>. Accessed May 19, 2011.
2. American Society of Plastic Surgeons. Report of the 2010 Plastic Surgery Statistics. Available at http://www.plasticsurgery.org/Documents/Media/2010-Statistics/ASPS_2010_Plastic_Surgery_Statistics_20711.pdf. Accessed May 19, 2011.
3. Oxford Centre for Evidence Based Medicine. Levels of Evidence. Available at: <http://www.cebm.net/index.aspx?o=1025>. Accessed August 30, 2010.
4. Prevention and Control of Healthcare-Associated Infections in Massachusetts. Part 1: Final Recommendations of the Expert Panel. Available at http://www.mass.gov/Eeohhs2/docs/dph/patient_safety/haipcp_final_report_pt1.doc. Accessed April 12, 2011.
5. Rosson GD, Magarakis M, Shridharani SM, et al. A review of the surgical management of breast cancer: plastic reconstructive techniques and timing implications. *Ann Surg Oncol*. 2010 Jul;17(7):1890-900.
6. Chun YS, Verma K, Rosen H, et al. Implant-based breast reconstruction using acellular dermal matrix and the risk of postoperative complications. *Plast Reconstr Surg*. 2010 Feb;125(2):429-36.
7. Alderman AK, Jagsi R. Discussion: Immediate post-mastectomy breast reconstruction followed by radiotherapy: risk factors for complications. *Breast Cancer Res Treat*. 2010 Jun;121(3):635-7.
8. Kronowitz SJ. Delayed-immediate breast reconstruction: technical and timing considerations. *Plast Reconstr Surg*. 2010 Feb;125(2):463-74.
9. Lee CN, Hultman CS, Sepucha K. What are patients' goals and concerns about breast reconstruction after mastectomy? *Ann Plast Surg*. 2010 May;64(5):567-9.
10. Adesiyun TA, Lee BT, Yueh JH, et al. Impact of Sequencing of Postmastectomy Radiotherapy and Breast Reconstruction on Timing and Rate of Complications and Patient Satisfaction. *Int J Radiat Oncol Biol Phys*. 2011 Jun 1;80(2): 392-7.
11. Anderson PR, Freedman G, Nicolaou N, et al. Postmastectomy chest wall radiation to a temporary tissue expander or permanent breast implant--is there a difference in complication rates? *Int J Radiat Oncol Biol Phys*. 2009 May 1;74(1):81-5.
12. Cordeiro PG, McCarthy CM. A single surgeon's 12-year experience with tissue expander/implant breast reconstruction: part I. A prospective analysis of early complications. *Plast Reconstr Surg*. 2006 Sep 15;118(4):825-31.
13. Kronowitz SJ, Robb GL. Radiation therapy and breast reconstruction: a critical review of the literature. *Plast Reconstr Surg*. 2009;124:395-408.
14. Krueger EA, Wilkins EG, Strawderman M, et al. Complications and patient satisfaction following expander/implant breast reconstruction with and without radiotherapy. *Int J Radiat Oncol Biol Phys*. 2001 Mar 1;49(3):713-21.
15. Nahabedian MY, Tsangaris T, Momen B, Manson PN. Infectious complications following breast reconstruction with expanders and implants. *Plast Reconstr Surg*. 2003 Aug;112(2):467-76.
16. Spear SL, Boehmler JH, Bogue DP, Mafi AA. Options in reconstructing the irradiated breast. *Plast Reconstr Surg*. 2008 Aug;122(2):379-88.
17. Nahabedian MY. Breast reconstruction: a review and rationale for patient selection. *Plast Reconstr Surg*. 2009 Jul;124(1):55-62.

18. American Society of Plastic Surgeons. Report of the 2010 Plastic Surgery Statistics. Available at http://www.plasticsurgery.org/Documents/Media/2010-Statistics/ASPS_2010_Plastic_Surgery_Statistics_20111.pdf. Accessed May 19, 2011.
19. Al-Ghazal SK, Sully L, Fallowfield L, Blamey RW. The psychological impact of immediate rather than delayed breast reconstruction. *Eur J Surg Oncol*. 2000 Feb;26(1):17-9.
20. Cordeiro PG, McCarthy CM. A single surgeon's 12-year experience with tissue expander/implant breast reconstruction: part II. An analysis of long-term complications, aesthetic outcomes, and patient satisfaction. *Plast Reconstr Surg*. 2006 Sep 15;118(4):832-9.
21. Nahabedian MY, Momen B, Galdino G, Manson PN. Breast Reconstruction with the free TRAM or DIEP flap: patient selection, choice of flap, and outcome. *Plast Reconstr Surg*. 2002 Aug;110(2):466-75; discussion 476-7.
22. Pinsolle V, Grinfeder C, Mathoulin-Pelissier S, Faucher A. Complications analysis of 266 immediate breast reconstructions. *J Plast Reconstr Aesthet Surg*. 2006;59:1017-24.
23. Yueh JH, Slavin SA, Adesiyun T, et al. Patient satisfaction in postmastectomy breast reconstruction: a comparative evaluation of DIEP, TRAM, latissimus flap, and implant techniques. *Plast Reconstr Surg*. 2010 Jun;125(6):1585-95.
24. Lee BT, T AA, Colakoglu S, et al. Postmastectomy radiation therapy and breast reconstruction: an analysis of complications and patient satisfaction. *Ann Plast Surg*;64:679-83.
25. Kronowitz SJ, Kuerer HM. Advances and surgical decision-making for breast reconstruction. *Cancer*. 2006;107:893-907.
26. O'Leary KA, Estabrooks CA, Olson K, Cumming C. Information acquisition for women facing surgical treatment for breast cancer: influencing factors and selected outcomes. *Patient Education and Counseling*. 2007;69:5-19.
27. Alderman AK, Hawley ST, Waljee J, Mujahid M, Morrow M, Katz SJ. Understanding the impact of breast reconstruction on the surgical decision-making process for breast cancer. *Cancer*. 2008;112:489-94.
28. Temple CL, Cook EF, Ross DC, Bettger-Hahn M, MacDermid J. Development of a breast reconstruction satisfaction questionnaire (BRECON): dimensionality and clinical importance of breast symptoms, donor site issues, patient expectations, and relationships. *J Surg Oncol*. 2010;101:209-16.
29. Katz SJ, Lantz PM, Janz NK, et al. Patient involvement in surgery treatment decisions for breast cancer. *J Clin Oncol*. 2005;23:5526-33.
30. Stacey D, Samant R, Bennett C. Decision making in oncology: a review of patient decision aids to support patient participation. *CA Cancer J Clin*. 2008;58:293-304.
31. Tariman JD, Berry DL, Cochrane B, Doorenbos A, Schepp K. Preferred and actual participation roles during health care decision making in persons with cancer: a systematic review. *Ann Oncol*. 2010;21:1145-51.
32. Pusic AL, Chen CM, Cano S, et al. Measuring quality of life in cosmetic and reconstructive breast surgery: a systematic review of patient-reported outcomes instruments. *Plast Reconstr Surg*. 2007;120:823-37; discussion 38-9.
33. Lee C, Sunu C, Pignone M. Patient-reported outcomes of breast reconstruction after mastectomy: a systematic review. *J Am Coll Surg*. 2009;209:123-33.
34. Winters ZE, Benson JR, Pusic AL. A systematic review of the clinical evidence to guide treatment recommendations in breast reconstruction based on patient-reported outcome measures and health-related quality of life. *Ann Surg*. 2010;Epub ahead of print.
35. Alderman AK, Kuhn LE, Lowery JC, Wilkins EG. Does patient satisfaction with breast reconstruction change over time? Two-year results of the Michigan Breast Reconstruction Outcomes Study. *J Am Coll Surg*. 2007;204:7-12.

36. Lee CN, Dominik R, Levin CA, et al. Development of instruments to measure the quality of breast cancer treatment decisions. *Health Expect*. 2010;13:258-72.
37. Farmer AP, Legare F, Turcot L, et al. Printed educational materials: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*. 2008;CD004398.
38. O'Connor AM, Bennett CL, Stacey D, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2009;CD001431.
39. Whelan T, Levine M, Willan A, et al. Effect of a decision aid on knowledge and treatment decision making for breast cancer surgery: a randomized trial. *JAMA*. 2004;292:435-41.
40. Waljee JF, Rogers MA, Alderman AK. Decision aids and breast cancer: do they influence choice for surgery and knowledge of treatment options? *J Clin Oncol*. 2007;25:1067-73.
41. Preminger BA, Lemaine V, Sulimanoff I, Pusic AL, McCarthy CM. Preoperative Patient Education for Breast Reconstruction: A Systematic Review of the Literature. *J Cancer Educ*. 2010.
42. Heller L, Parker PA, Youssef A, Miller MJ. Interactive digital education aid in breast reconstruction. *Plast Reconstr Surg*. 2008;122:717-24.
43. Lee BT, Chen C, Yueh JH, Nguyen MD, Lin SJ, Tobias AM. Computer-based learning module increases shared decision making in breast reconstruction. *Ann Surg Oncol*. 2010;17:738-45.
44. *Foundation for Informed Medical Decision Making*. Breast Cancer Initiative. Available at http://www.informedmedicaldecisions.org/breast_cancer_initiative.html. Accessed May 4, 2011.
45. Fernandez Delgado JM, Martinez-Mendez JR, de Santiago J, Hernandez-Cortes G, Casado C. Immediate breast reconstruction (IBR) with direct, anatomic, extra-projection prosthesis: 102 cases. *Ann Plast Surg*. 2007;58:99-104.
46. Pittet B, Montandon D, Pittet D. Infection in breast implants. *Lancet Infect Dis*. 2005;5:94-106.
47. Sullivan SR, Fletcher DR, Isom CD, Isik FF. True incidence of all complications following immediate and delayed breast reconstruction. *Plast Reconstr Surg*. 2008;122:19-28.
48. McCarthy CM, Mehrara BJ, Riedel E, et al. Predicting complications following expander/implant breast reconstruction: an outcomes analysis based on preoperative clinical risk. *Plast Reconstr Surg*. 2008;121:1886-92.
49. Francis SH, Ruberg RL, Stevenson KB, et al. Independent risk factors for infection in tissue expander breast reconstruction. *Plast Reconstr Surg*. 2009;124:1790-6.
50. Antony AK, McCarthy CM, Cordeiro PG, et al. Acellular human dermis implantation in 153 immediate two-stage tissue expander breast reconstructions: determining the incidence and significant predictors of complications. *Plast Reconstr Surg*. 2010;125:1606-14.
51. Becker S, Saint-Cyr M, Wong C, et al. AlloDerm versus DermaMatrix in immediate expander-based breast reconstruction: a preliminary comparison of complication profiles and material compliance. *Plast Reconstr Surg*. 2009;123:1-6; discussion 107-8.
52. Nguyen MD, Chen C, Colakoglu S, Morris DJ, Tobias AM, Lee BT. Infectious Complications Leading to Explantation in Implant-Based Breast Reconstruction With AlloDerm. *Eplasty*. 2010;10:e48.
53. Sbitany H, Sandeen SN, Amalfi AN, Davenport MS, Langstein HN. Acellular dermis-assisted prosthetic breast reconstruction versus complete submuscular coverage: a head-to-head comparison of outcomes. *Plast Reconstr Surg*. 2009;124:1735-40.
54. Spear SL, Parikh PM, Reisin E, Menon NG. Acellular dermis-assisted breast reconstruction. *Aesthetic Plast Surg*. 2008;32:418-25.
55. *Safety Alerts for Human Medical Products*. Breast Implants: FDA Review Indicates Possible Association With A Rare Cancer. Available at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm241101.htm>. Accessed February 16, 2011.

56. Spear SL, Seruya M. Management of the infected or exposed breast prosthesis: a single surgeon's 15-year experience with 69 patients. *Plast Reconstr Surg*. 2010;125:1074-84.
57. McCarthy CM, Disa JJ, Pusic AL, Mehrara BJ, Cordeiro PG. The effect of closed-suction drains on the incidence of local wound complications following tissue expander/implant reconstruction: a cohort study. *Plast Reconstr Surg*. 2007;119:2018-22.
58. Jain PK, Sowdi R, Anderson AD, MacFie J. Randomized clinical trial investigating the use of drains and fibrin sealant following surgery for breast cancer. *Br J Surg*. 2004;91:54-60.
59. Ezeome ER, Adebamowo CA. Closed suction drainage versus closed simple drainage in the management of modified radical mastectomy wounds. *S Afr Med J*. 2008;98:712-5.
60. Murray JD, Elwood ET, Jones GE, Barrick R, Feng J. Decreasing expander breast infection: A new drain care protocol. *Can J Plast Surg*. 2009;17:17-21.
61. Akinci M, Cetin B, Aslan S, Kulacoglu H. Factors affecting seroma formation after mastectomy with full axillary dissection. *Acta Chir Belg*. 2009;109:481-3.
62. Barton A, Blitz M, Callahan D, Yakimets W, Adams D, Dabbs K. Early removal of postmastectomy drains is not beneficial: results from a halted randomized controlled trial. *Am J Surg*. 2006;191:652-6.
63. Barwell J, Campbell L, Watkins RM, Teasdale C. How long should suction drains stay in after breast surgery with axillary dissection? *Ann R Coll Surg Engl*. 1997;79:435-7.
64. Kopelman D, Klemm O, Bahous H, Klein R, Krausz M, Hashmonai M. Postoperative suction drainage of the axilla: for how long? Prospective randomised trial. *Eur J Surg*. 1999;165:117-20; discussion 21-2.
65. Olsen MA, Lefta M, Dietz JR, et al. Risk factors for surgical site infection after major breast operation. *J Am Coll Surg*. 2008;207:326-35.
66. The Joint Commission. *Focused Practitioner Performance Evaluation*. Available at http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=76&StandardsFAQChapterId=25. Accessed May 18, 2011.
67. Blichert-Toft M, Christiansen P, Mouridsen HT. Danish Breast Cancer Cooperative Group--DBCG: History, organization, and status of scientific achievements at 30-year anniversary. *Acta Oncol*. 2008;47:497-505.
68. UK National Health Service Information Centre. Breast Cancer-Collaborative Initiative. A national audit of provision and outcomes of mastectomy and breast reconstruction surgery for women in England Fourth Annual Report 2011. Available at <http://www.ic.nhs.uk/services/national-clinical-audit-support-programme-ncasp/audit-reports/mastectomy-and-breast-reconstruction>. Accessed May 18, 2011.
69. Ingraham AM, Richards KE, Hall BL, Ko CY. Quality improvement in surgery: the American College of Surgeons National Surgical Quality Improvement Program approach. *Adv Surg*. 2010; 44:251-67.
70. Wright CD, Edwards FH; Society of Thoracic Surgeons General Thoracic Surgery Database Task Force; Society of Thoracic Surgeons Workforce on National Databases. The Society of Thoracic Surgeons General Thoracic Surgery Database. *Ann Thorac Surg*. 2007 Mar;83(3):893-4.
71. Bridgewater B, Kinsman R, Walton P, Gummert J, Kappetein AP. The 4th European Association for Cardio-Thoracic Surgery adult cardiac surgery database report. *Interact Cardiovasc Thorac Surg*. 2011 Jan;12(1):4-5
72. Schirmer B, Jones DB. The American College of Surgeons Bariatric Surgery Center Network: establishing standards. *Bull Am Coll Surg*. 2007;92:21-7.

73. Guidelines for institutions granting bariatric privileges utilizing laparoscopic techniques. Society of American Gastrointestinal Endoscopic Surgeons (SAGES) and the SAGES Bariatric Task Force. *Surg Endosc*. 2003;17:2037-40.
74. Bariatric surgery. *Clin Privil White Pap*. 1998:1-6.
75. CMS Research, Statistics, Data & Systems. Available at: <https://www.cms.gov/home/rsds.asp> Accessed February 28, 2011.
76. Sbitany H, Amalfi AN, Langstein HN. Preferences in choosing between breast reconstruction options: a survey of female plastic surgeons. *Plast Reconstr Surg* 2009;124:1781-9.

BREAST RECONSTRUCTION GLOSSARY

Acellular Dermal Matrix: A human dermis-derived allograft material. Acellular dermal matrix (ADM) is derived from human cadaveric dermis from which the epidermis, all viable cells and major histocompatibility class (MHC) II antigens have been removed to minimize alloimmunogenicity, while the dermal collagen matrix is preserved. ADM may be placed over wounds to aid as a substitute for skin when necessary such as for surgical reconstruction or for protection against wound exposure and breakdown and wound infection.

Adjuvant Therapy: Treatment provided in early breast cancer in addition to the primary surgery in an effort to increase its effectiveness, i.e., radiation and chemotherapy.

Allograft: A graft of tissue obtained from a donor genetically different from, though of the same species as the recipient.

Autologous: involving one donor as both donor and recipient; derived or transferred from the same person's body.

Biologics: Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies.

Capsular Contracture: A complication of breast implant surgery which occurs when scar tissue that normally forms around the implant squeezes the implant and becomes firm. There are 4 grades of contracture (Grades I - IV) that range from normal and soft to hard, painful, and distorted.

Cellulitis: diffuse and especially subcutaneous inflammation of connective tissue.

Delayed Reconstruction: reconstructive surgery that is done at a later time, not at the time of the mastectomy.

DIEP (Deep Inferior Epigastric Artery Perforator) Flap: a breast reconstruction procedure that uses blood vessels called deep inferior epigastric perforators (DIEP), fat and skin from the lower abdomen. Unlike the TRAM flap, it does not use the abdominal muscle to form the breast mound.

Erythema: abnormal redness of the skin due to capillary congestion

Free Flap: in this kind of surgery the tissue for reconstruction is moved entirely from another area of the body and the blood and nerve supplies are surgically reattached with special microscopes.

Gluteal Free Flap: a newer type of flap procedure that uses tissue and gluteal muscle from the buttocks to create the breast shape.

Hematoma: A localized swelling filled with blood resulting from a break in a blood vessel.

Inframammary Fold: the crease under the breast, where the breast and chest wall meet.

Immediate breast reconstruction: reconstructive surgery that is done at the same time as the mastectomy.

Implant-Based Reconstruction: a method of breast construction that utilizes an implant to reconstruct the breast. This procedure is accomplished in a single stage, with placement of the implant at the time of the reconstructive surgery; or two stages, with placement of a tissue expander and a subsequent procedure to replace the expander with the implant.

Latissimus Dorsi Flap: this procedure tunnels muscle, fat, and skin from the upper back to the chest to create a breast mound.

Lumpectomy: surgery that removes only the breast lump and a rim (margin) of normal tissue around it.

Necrosis: cell and tissue death from lack of blood supply to the tissue.

Nipple-Sparing Mastectomy: procedure that allows the nipple, areola, and much of the breast skin to be preserved during mastectomy to make reconstruction easier.

Neoadjuvant Therapy: treatment prescribed to a patient before the main treatment, such as chemotherapy prescribed to shrink a breast tumor before surgery

Nonptotic: See ptosis.

Pedicle Flap: tissue that is surgically removed, but the blood vessels remain attached and are tunneled from the original site to the area where the tissue is to be attached.

Ptosis: Ptosis of the breast refers to drooping or sagging of the breast.

Radiation Therapy: a form of cancer treatment that uses high levels of radiation to kill cancer cells or keep them from growing and dividing, while minimizing damage to healthy cells.

Saline Implants: Breast implants filled with a salt water solution.

Seroma: A mass or swelling caused by the localized accumulation of serum within a tissue or organ seroma.

Sentinel Lymph Node: The first lymph node to which a tumor drains, making it the first place where cancer is likely to spread. In breast cancer, the sentinel node is usually located in the axillary nodes, located under the arm.

SIEA (Superficial Inferior Epigastric Artery) Flap: a breast reconstruction procedure similar to the DIEP flap technique, that uses the superficial inferior epigastric blood vessels, and skin and fat from the abdomen to replace the soft tissue removed in a mastectomy.

Silicone Gel-Filled Implants: breast implants filled with a man-made material called silicone.

Submammary or Subglandular Placement: Breast implants placed directly behind the breast tissue, over the pectoral muscle.

Submuscular or Subpectoral Placement: Breast implants placed under the pectoral muscle, which is located between the breast tissue and chest wall.

Tissue Expansion: A procedure that can substitute for skin grafts. An inflatable balloon called a tissue expander is placed under the skin near the scar site to stretch additional skin to be used to revise a scar. Oftentimes, multiple procedures are needed.

Tissue Expander: implanted balloons under the skin are used to keep living tissues under tension. This causes new cells to form and stretches the tissue. The surgeon puts the expander beneath the skin where the breast should be and over weeks or months, injects a saline solution to slowly expand the overlaying skin to make space for an implant.

Tissue Flap Reconstruction: tissue for reconstruction that is surgically removed from another area of the body. It can be a pedicle (left attached to its base and then tunneled) or free flap (cut free from its base and transplanted to the chest).

TRAM (Transverse Rectus Abdominis Muscle) Flap: a breast reconstruction procedure that uses tissue and muscle from the lower abdominal wall to reconstruct a breast mound. It can be a pedicle (left attached to its base and then tunneled) or free flap (cut free from its base and transplanted to the chest).

Two-Stage Reconstruction: a two-step procedure in which a tissue expander is placed beneath the skin and chest muscle. The expander is slowly filled with saline over time and surgically replaced with an implant when it expands to full size.

APPENDIX A

TECHNICAL CONSIDERATIONS IN IMPLANT-BASED BREAST RECONSTRUCTION

Twelve plastic surgeons participated on the *Expert Panel to Review Immediate Implant Based Reconstruction following Mastectomy for Cancer*. All members have between four and twenty-two years experience as attending surgeons, and all specialize in performing immediate and delayed breast reconstruction procedures. Surgeons who perform both implant-based and autologous reconstructions were represented.

All participating plastic surgeons were polled via survey as to surgical preferences in order to determine where common practice exists. The following is a review of the survey results, as well as a discussion of general principles of surgical practice for implant-based breast reconstruction. This report is not intended to recommend best practice. Definitive recommendations can only be made after empirical prospective evidence has been collected. Rather it is an effort to encourage surgeons to establish protocols for this area of surgical practice and to move the discussion toward establishing a standard of care. The Panel recognizes that surgeons make decisions based on what works in their hands; and that variations in technique can result in equivalent, reproducible, and acceptable outcomes.

A. Technical Considerations in Mastectomy

Native skin flap perfusion problems can be a factor in postoperative complications. Meticulous surgical technique by the surgical oncologist can prevent complications that could lead to Surgical Site Infections. While the ablative procedure should not be compromised for the reconstruction, it is usually possible to perform an adequate ablation without creating uncorrectable deformities.

Placement of lumpectomy and biopsy incisions must be carefully considered while keeping in mind the potential need for a future skin-sparing mastectomy. Skin-sparing mastectomy techniques require the creation of large undermined flaps with a random-patterned blood flow. Extreme care must be taken to avoid uneven flap thickness, step off deformities at the dissection borders, and crush injuries from overzealous retraction. Over-resection of the distal pectoral muscle fibers should be avoided. Dissection beyond the borders of the breast can be avoided by careful preoperative marking by the surgical oncologist. Excessively wide dissection often creates deformities remote from the breast itself that make implant reconstruction alone very difficult, if not impossible.

The plastic surgeon is responsible for determining flap viability, at the start of the reconstruction. All irreversibly damaged tissue must be debrided. Many complications are caused by retained poorly-perfused native skin at the margins of the incisions. To that end, all survey participants agreed that skin flap necrosis should be debrided and delayed primary closure performed as soon as the involved area has clearly demarcated (usually within 7-14 days).

B. Intraoperative Factors that Reduce Perioperative Complications

Recommendations for prevention of surgical site infection (SSI) following mastectomy and breast reconstruction are included in the Panel's report. (Appendix B). The following is a

discussion of measures used by the members of the Panel that are consistent with these recommendations.

Skin Disinfection

Chlorhexidine gluconate plus an isopropyl alcohol agent is preferred over povidone-iodine alone for skin preparation. The deep resident bacteria in the skin appendages such as hair follicles and glands cannot be removed by skin preparation. To prevent field contamination during the mastectomy, some surgeons have suggested covering the nipple areola complex with Tegaderm or Opsite. These films adhere longer to a dry surface coated with Mastisol prior to the incision.

Peri-operative Antibiotic Prophylaxis

Consistent with the Panel's recommendations for SSI prevention, all surgeons surveyed routinely prescribe peri-operative antibiotic prophylaxis. Cefazolin is generally dosed at 1 or 2 grams based on weight, with redosing at four hours or sooner if there is significant blood loss. For patients with beta-lactam allergy, 80% of the survey respondents give Clindamycin. Vancomycin is reserved for use for specific clinical circumstances. For example, nine surgeons surveyed give Vancomycin to patients with a history of MRSA colonization or infection. Time out procedures should include a review of perioperative antibiotics given and the plan for re-dosing.

Intraoperative Antibiotic Irrigation

All surgeons answering the survey perform intraoperative irrigation. Seventy-five percent (75%) of respondents use Bacitracin-laced irrigation. Half of the remaining surgeons use triple antibiotic solution and the others use sterile saline.

Post-operative Oral Antibiotics

The need for and duration of post-operative antibiotic prophylaxis has long been debated. There is currently no evidence to support firm recommendation for prophylactic antibiotics beyond 24 hours. All surgeons surveyed reported that they routinely prescribe a postoperative course of antibiotics until the drains are removed.

Patient Warming

All surgeons polled reported that they employ warming methods including continuous core temperature monitoring, Baer warm air blankets, blanket layering under the drapes, circulating warm water pads, IV fluid warmers, warm irrigation, room warming, and warmed humidified air in the anesthesia circuits.

Use of Drains

All of the surgeons responding to the survey place drains. Whether 1 or 2 drains per breast are used depends on the size of the mastectomy defect and whether the surgeon can adequately reach all areas with a single drain. Most of the surgeons surveyed (75%) remove the drains when the output is < 30 cc per day. The remaining respondents (25%) wait until output is <20cc per day.

C. Immediate Reconstruction with Expanders

Expander selection

Two-thirds of the surgeons surveyed prefer an anatomic device. The advantage of this is that the majority of the expansion occurs behind the apex of the new breast mound where maximal

projection is desired. An anatomic device also creates more fullness and definition of the lower pole. There was no clear choice in terms of expander manufacturer. The general consensus is that the surgeon should select a device that provides the best results in his or her hands. The surgeons who chose round devices generally over-expand the devices. This is potentially easier with the round devices because the silicone envelope is thinner and more easily distensible.

Placement

Two-thirds of surgeons place the expander under the pectorals muscle alone. Advantages of this approach include less aggressive dissection, potentially less postoperative pain, and elimination of serratus strain which may cause flattening of the lateral aspect of the lower pole after definitive implant reconstruction. Also, this may facilitate use of a wide diameter expander in the patient who requires a high volume implant reconstruction.

Advantages of placement under both pectoral and serratus muscles include stabilization of the lateral aspect of the pectoralis muscle, complete muscle coverage under the mastectomy incision, better control of the final breast mound position particularly when the mastectomy dissection extends posteriorly beyond the midaxillary line, and thickening of implant coverage under very thin lateral skin flaps.

In general, it is desirable to avoid denervation of both muscles during mastectomy and reconstruction in order to preserve muscle function and thickness.

None of the plastic surgeons surveyed routinely fixate anatomic devices at the intramammary fold (IMF).

Intraoperative filling

With respect to intraoperative fill volume, a good rule of thumb is to fill approximately to 1/3 of the end-volume of the device, adjusting the amount to avoid undue tension on the overlying pectoralis muscle and overlying skin. Avoiding excessive tension intraoperatively reduces pain and spasm in the immediate perioperative period and helps to reduce patient anxiety for the remaining serial fills. Filling should be performed after the skin closure to adequately assess skin perfusion and changes that may occur with increasing volume.

Anatomic devices have a relatively thick silicone shell and a firm, rubberized posterior surface compared to round devices, which means that when deflated stiff folds, edges and corners are formed. This solid plate-like structure is uncomfortable when rubbing against the underlying ribs and periosteum. Even when there is significant tension on the skin and muscle, some filling (50-100 ml) may be beneficial, to soften the device. This should not produce a significant amount of anterior pressure on the overlying soft tissues, but will reduce postoperative discomfort.

Serial Filling in the Office

Timing

None of the surgeons surveyed began filling the devices prior to the fourteenth postoperative day, with a mean of three weeks. All surgeons agreed that expansion should be deferred until any skin perfusion issue has been resolved and healing is well-underway.

Fill Protocol

In the office, the fill ports should be marked, and the overlying skin disinfected 3 times with alcohol swabs (Central Line correlate). Povidine iodine solution can be substituted, but must be allowed to dry prior to injection to be effective. The amount injected at each visit should be adjusted to patient comfort, and overlying skin perfusion.

Approximately 50 % of the surgeons surveyed overfill the expanders. The stated advantage of this is the creation of a large skin envelope which allows for 1) the creation of ptosis or 2) breast enlargement relative to preoperative breast size the at the time of definitive implant reconstruction. The amount of overfilling should take patient comfort into consideration. The remaining respondents do not overfill and believe that with capsulotomy and partial capsulectomy techniques at the time of exchange, the ultimate implant volume can be significantly greater than the final expander volume. Overfilling can also result in more retrograde expansion into the chest cavity.

Expander to Implant Exchange Procedure Timing

The surgeons surveyed waited at least six weeks before exchanging devices. The mean duration was 3 months, and all deferred until chemotherapy was completed.

Special Considerations for Radiating Expanders

The Panel recommends that reconstruction be delayed in patients who require radiation therapy. In those circumstances when reconstruction is performed before the patient undergoes radiation therapy, the surgeon should consider placing the expander in a slightly lateral position and avoid overfilling, as retrograde expansion will result in the need to perpendicularly orient the beam to include the ribs, which have been pushed deeper into the chest cavity. The expander should be fully filled before the radiotherapy planning session. Occasionally, the surgeon is asked to deflate one or both of the devices to decrease radiation exposure to the heart, lungs, or opposite breast. The most common request is to deflate a right-sided device for left-sided radiation in a patient who has had a bilateral procedure.

D. Immediate Implant Reconstruction

Acellular Dermal Matrix

All but one surgeon surveyed uses acellular dermal matrix when performing immediate implant reconstruction. Acellular dermal matrix is used for positioning of the device and prevention of lateral dislocation of the device. Those that use acellular dermal matrix place the device under the pectoralis muscle alone, suturing the lateral border of the acellular dermal matrix directly to the superficial surface of the serratus. All of the surgeons surveyed use only a single piece of acellular dermal matrix. None of the surgeons practice “stacking” of multiple pieces of acellular dermal matrix. Fifty percent (50%) of the surgeons surveyed prefer to use thick acellular dermal matrix to improve soft tissue thickness in the hopes of reducing visible wrinkling. Those who prefer thin acellular dermal matrix, (25%), do so based on the theory that thin acellular dermal matrix integrates faster into the overlying soft tissues. Twenty-five percent of respondents had no preference with respect to thickness. Forty-three percent (43%) of surgeons placed the deep or dermal surface of the acellular dermal adjacent to the skin flap; again, the reasoning is that this facilitates integration. Twenty-nine percent (29%) of the respondents placed the deep surface of the acellular dermal matrix against the implant surface.

Implant Selection

All but one surgeon responding to the survey preferentially uses silicone implants. All twelve surgeons polled use smooth round devices. The explanation for this finding include the fact that the anatomic devices frequently visibly rotate. To prevent this complication, the surface of these devices is heavily textured which promotes adherence to the overlying capsule. When this occurs, there is more visible cranial wrinkling. Also, the gel in the anatomic implants is stiffer (more polymer cross-linking) to maintain a teardrop shape and is less natural feeling.

E. Treatment of Implant Infection

The diagnosis of implant infection was generally made by one or more of the following signs and symptoms: elevated temperature ($>99^{\circ}\text{C}$), breast swelling, increased discomfort, elevated white blood count (+/- left shift), and erythema in conjunction with another sign. (Erythema alone may be secondary to poor skin perfusion, venous congestion, aggressive expansion resulting in same, or localized lymphatic obstruction.) All surgeons reported that all four criteria would need to be met before they would remove the device.

Most respondents reported that they would rarely treat suspected surgical site infections with oral antibiotics alone. More than half the respondents would treat the patient empirically with intravenous vancomycin prior to obtaining definitive culture results. Only thirty-eight percent (38%) of respondents reported that they would attempt implant salvage. The majority of surgeons would remove the existing device without replacing it. They would wait at least 3 months (with a mean of 5 months) prior to performing secondary reconstruction with an expander.

Those surgeons that attempt salvage debride all fibrinous exudates and perform irrigation with an antibiotic solution (Ancef, Bacitracin, Gentamicin, or a combination). Eighty percent (80%) of the respondents remove the acellular dermal matrix, if present. Eighty percent (80%) would perform capsulectomy to increase pocket volume. Seventy-five percent (75%) replace the existing device with an expander. None of the respondents would replace the existing device after debridement and irrigation.

APPENDIX B

RECOMMENDATIONS FOR PREVENTION OF SURGICAL SITE INFECTIONS FOLLOWING MASTECTOMY AND BREAST RECONSTRUCTION

Based on Prevention and Control of Healthcare-Associated Infections in Massachusetts.

Part 1: Final Recommendations of the Expert Panel.

http://www.mass.gov/Eeohhs2/docs/dph/patient_safety/haipcp_final_report_pt1.doc

A. Preoperative

Preparation of the patient

1. Whenever possible, identify and treat all infections remote to the surgical site before elective operation and postpone elective operations on patients with remote site infections until the infection has resolved. *(CDC category IA) A-IV*
2. Do not remove hair preoperatively unless the hair at or around the incision site will interfere with the operation. *(CDC category IA) A-IV*¹
3. If hair is removed, remove immediately before the operation, preferably with electric clippers. Patients should be instructed not to shave the incision site within 48 hours prior to surgery. *(CDC category IA) A-IV*²
4. Adequately control serum blood glucose levels in all adult surgical patients and particularly avoid hyperglycemia perioperatively. The exact blood glucose levels to be maintained and the duration of the perioperative period are an unresolved issue. *B-I*^{3 4 5 6 7 8}
5. Encourage stopping use of tobacco products. At minimum, instruct patients to abstain for at least 30 days before elective operation from smoking cigarettes, cigars, pipes or any other form of tobacco consumption (e.g. chewing/dipping). *(CDC category IB) B-IV*
6. Do not withhold necessary blood products from surgical patients as a means to prevent SSI. *(CDC category IB) B-IV*
7. Preoperative showering or bathing with agents such as chlorhexidine has been shown to reduce bacterial colonization of the skin but has not definitively been proven to decrease SSI risk. If hospitals elect to use preoperative showering with chlorhexidine soap as an SSI strategy, staff responsible for pre-surgical evaluations shall educate patients on the appropriate showering technique. *(CDC category IB) UI*⁹ Preoperative showering or bathing with chlorhexidine in conjunction with intranasal mupirocin can also be considered as an adjunctive measure, but the effectiveness of decolonization of patients undergoing mastectomy and reconstruction for preventing SSI is unresolved (see #12)
8. Thoroughly wash and clean at and around the incision site to remove gross contamination before performing antiseptic skin preparation. *(CDC category IB) A-IV*
9. Use an appropriate antiseptic agent for skin preparation. Use a chlorhexidine gluconate plus isopropyl alcohol or an iodophor plus isopropyl alcohol agent preferentially over povidone-iodine alone. *A-I* The comparative effectiveness of chlorhexidine-alcohol compared to iodophor-alcohol combinations is unresolved. *UI*¹⁰
10. Apply preoperative antiseptic skin preparation using manufacturer's product guidelines. The prepared area must be large enough to extend the incision or create new incisions or drain sites, if necessary. *(CDC category II) A-IV*
11. Keep preoperative hospital stay as short as possible while allowing for adequate preoperative preparation of the patient. *(CDC category IB) B-IV*

12. The routine preoperative screening of patients for *Staphylococcus aureus* carriage and/or routine attempts to decolonize surgical patients with an antistaphylococcal agent in the preoperative setting is an unresolved issue. A double-blinded, randomized, controlled trial involving more than 4,000 patients showed that intranasal application of mupirocin did not significantly reduce the *S. aureus* SSI rate. In a secondary analysis of these data, however, the use of intranasal mupirocin was associated with an overall decreased rate of nosocomial *S. aureus* infection among *S. aureus* carriers. Other studies have shown that mupirocin may be effective for particular patient groups, including patients undergoing orthopedic or cardiothoracic surgery. However, these were not randomized trials. A recent randomized trial from the Netherlands demonstrated that decolonizing patients who were *S. aureus* carriers with a combination of intranasal mupirocin and chlorhexidine bathing/showering for five days led to a decrease in the overall rate of SSI due to *S. aureus*. In this study, there were no methicillin-resistant *S. aureus* carriers or *S. aureus* isolates with mupirocin resistance were identified, possibly limiting the generalizability of these results. Therefore, no recommendation for or against its preoperative use can be made at this time. **UI**^{11 12 13 14 15 16}

Hand/forearm antisepsis for surgical team members

13. Keep nails short and do not wear artificial nails. (CDC category IB) **B-IV**¹⁷
14. An FDA-compliant, surgical hand antiseptic agent (i.e. surgical hand scrub/rub) approved by the facility's infection control personnel should be used for all surgical hand antisepsis. Hands should be washed with plain or antimicrobial soap and running water immediately before beginning the surgical hand antisepsis/scrub. Hand scrub: Traditional antimicrobial scrub agent should include a standardized scrub procedure that follows the manufacturer's written directions for use and is approved by the health care facility. A traditional, standardized anatomical, timed or counted stroke method may be used for surgical hand antisepsis/scrub. Hand rub: Standardized protocol for alcohol based surgical hand rubs should follow manufacturer's written instructions and include washing hands and forearms with soap and running water before beginning the surgical hand antisepsis procedure. (CDC category IB) **B-IV**¹⁷
15. After performing the surgical scrub, keep hands up and away from the body (elbows in flexed position) so that water runs from the tips of the fingers toward the elbows. Dry hands with a sterile towel and put on a sterile gown and gloves. If alcohol hand antisepsis is used, allow hands to dry before donning gloves. (CDC category IB) **B-IV**
16. For both types of surgical hand antisepsis, clean underneath each fingernail prior to performing the first surgical scrub/rub of the day. (CDC category II) **B-IV**
17. Scrubbed personnel should not wear hand or arm jewelry. (CDC category II) **B-IV**
18. Nail polish, if used, should not be chipped. Available data indicate that nail polish that has been obviously chipped or worn for more than four days harbors greater numbers of bacteria. (CDC category UI) **A-IV**¹⁷

Management of infected or colonized surgical personnel

19. Develop and implement well-defined policies concerning patient care responsibilities when personnel have potentially transmissible infectious conditions. These policies should govern (a) personnel responsibility in using the health service and reporting illness, (b) work restrictions, and (c) clearance to resume work after an illness that required work restriction.

The policies also should identify persons who have the authority to remove personnel from duty. (CDC category IB) **A-IV**

20. Obtain appropriate cultures from, and exclude from duty, surgical personnel who have draining skin lesions until infection has been ruled out or personnel have received adequate therapy and infection has resolved. (CDC category IB) **B-IV**
21. Do not routinely exclude surgical personnel who are colonized with organisms such as *Staphylococcus aureus* (nose, hands, or other body site) or group A *Streptococcus*, unless such personnel have been linked epidemiologically to dissemination of the organism in the healthcare setting. (CDC category IB) **B-IV**

Antimicrobial prophylaxis

22. Administer prophylactic antimicrobial agents for mastectomy and breast reconstruction surgical procedures involving surgical incisions. Use an antimicrobial agent with anti-*Staphylococcus aureus* activity, such as cefazolin, and dose appropriately based on patient weight. Reserve vancomycin use for specific clinical circumstances, such as a proven outbreak of SSI due to MRSA, high endemic rates of SSI due to MRSA, targeted high-risk patients who are at increased risk for SSI due to MRSA, and high-risk surgical procedures during which an implant is placed. No definitions for “high endemic rates of SSI due to MRSA” have been established. No study has prospectively analyzed the effect of providing both glycopeptides and β -lactam antimicrobials for preoperative antimicrobial prophylaxis. (CDC category IA) **A-IV**^{18 19 20}
23. Administer by the intravenous route the initial dose of prophylactic antimicrobial agent, timed such that an effective concentration of the drug is established in serum and tissues when the incision is made. Maintain therapeutic levels of the agent in serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room. Prophylactic antibiotic should be received within one hour prior to surgical incision (vancomycin within 2 hours). Subsequent intraoperative doses of antibiotics should be administered as needed based on the pharmacokinetic profiles of the prophylactic agents being used. The duration of antibiotic prophylaxis should be in accordance with national guidelines. There is no evidence to support continuation of prophylactic antibiotics beyond 24 hours for patients who have drains in place. (CDC category IA) **A-IV**^{18 19 21 22 23 24 25}
24. Consider weight-based dosing of antimicrobial agents used for perioperative prophylaxis. If cefazolin is administered, consider using 1 gram IV for patients weighing ≤ 60 kg and 2 grams IV for patients weighing > 60 kg. If vancomycin is administered, consider weight-based dosing using 10-15 mg/kg IV infused slowly over 60-120 minutes. **XX**^{26 27 28}
25. Consider intraoperative redosing of antimicrobial prophylaxis agents for long procedures within approximately two serum half-lives of the antimicrobial agent (e.g., redose cefazolin intraoperatively every 4 hours). **XX**^{29 30 31}

B. Intraoperative

Ventilation

25. Maintain positive-pressure ventilation in the operating room with respect to the corridors and adjacent areas. (CDC category IB) **B-IV**
26. Maintain a minimum of 15 air changes per hour, of which at least 3 should be fresh air. (CDC category IB) **B-IV**
27. Filter all air, recirculated and fresh, through the appropriate filters per the Facility Guidelines Institute recommendations. (CDC category IB) **B-IV**³²

28. Introduce all air at the ceiling, and exhaust near the floor. (CDC category IB) **B-IV**
29. Keep operating room doors closed except as needed for passage of equipment, personnel, and the patient. (CDC category IB) **B-IV**
31. Limit the number of personnel entering the operating room to necessary personnel. (CDC category II) **B-IV**

Cleaning and disinfection of environmental surfaces

32. Cleaning should be performed on a regular basis to reduce the amount of dust, organic debris, and microbial load in surgical environments. After each surgical procedure a safe, clean environment should be reestablished. Operating rooms in which procedures may be performed should be terminally cleaned once daily, regardless of use. Operating room equipment and furniture that are visibly soiled, and surfaces of equipment that are touched by personnel while they are providing patient care or handling contaminated items, (such as anesthesia equipment), should be cleaned with an EPA- registered hospital- grade germicidal agent at the end of each surgical procedure. **B-IV**¹⁷

Microbiologic sampling

33. Do not perform routine environmental sampling of the OR. Perform microbiologic sampling of operating room environmental surfaces or air only as part of an epidemiologic investigation. (CDC category IB) **B-IV**

Sterilization of surgical instruments

34. Sterilize all surgical instruments according to published guidelines. (CDC category IB) **B-IV**
35. Flash Sterilization should be used only in carefully selected clinical situations where certain parameters are met.
 - Work practices dictating proper cleaning and decontamination, inspection and arrangement of instruments in the sterilizing tray or containers are followed.
 - Sterilization parameters are monitored and are consistent with sterilization guidelines issued by AAMI, AORN, and manufacturer of items to be sterilized.
 - Mechanisms are in place for direct delivery of sterilized items to the point of use.
 - Defined procedures for aseptic handling and personnel safety during transfer of sterilized items to the point of use are followed and audited.
 - Documentation mechanism in place to identify surgical procedures that had flash sterilized supplies provided for use.
 - Hospitals should monitor flash sterilization reprocessing and provide this data to a patient oversight committee in the hospital. (e.g. infection control, quality assurance, performance improvement or patient safety) at least annually.
 - Hospitals may wish to monitor by calculating a flash sterilization rate (# of flash loads per month/#cases per month X100)
 - Implants should not undergo routine flash sterilization except under emergent conditions. A rapid biological test should be performed during the process.
 - Flash sterilization should not be used for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time (CDC category IB) **B-IV**¹⁷

Surgical attire and drapes

36. Wear a surgical mask that fully covers the mouth and nose when entering the operating room if an operation is about to begin or already under way or if sterile instruments are

exposed or a sterile field has been established. Wear the mask throughout the operation. (This recommendation is in keeping with OSHA regulations that “require masks in combination with protective eyewear, such as goggles or glasses with solid shields, or chin-length face shield be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious material may be generated and eye, nose, or mouth contamination can be reasonably anticipated” in addition to “longstanding surgical tradition”.) (CDC category IB) **B-IV**

37. Wear a cap or hood to fully cover hair on the head and face when entering the operating room. (CDC category IB) **A-IV**
38. Do not wear shoe covers for the prevention of SSI (however, shoe covers are required by OSHA regulations when “gross contamination can reasonably be anticipated”) (CDC category IB) **A-IV**
39. Wear sterile gloves if a scrubbed surgical team member. Put on gloves after putting on a sterile gown. Wearing two pairs of gloves (double-gloving) has been shown to reduce hand contact with patients’ blood and body fluids when compared to wearing only a single pair. (CDC category IB) **A-IV**
40. Use surgical gowns and drapes that are effective barriers when wet (i.e., materials that resist liquid penetration). (CDC category IB) **A-IV**
41. Change scrub suits that are visibly soiled, contaminated and/or penetrated by blood or other potentially infectious materials. (per OSHA regulations, if a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible) (CDC category IB) **A-IV**
42. No recommendations on how or where to launder scrub suits, restricting use of scrub suits to the operating suite or for covering scrub suits when out of the operating suite. Home laundering of visibly soiled surgical attire is not recommended. (CDC category UI) **UI**

Asepsis and surgical technique

43. Adhere to standard principles of operating room asepsis as well as to relevant practice guidelines (i.e. recommendations for preventing central line associated bloodstream infections, USP 797) when placing intravascular devices (e.g., central venous catheters), spinal or epidural anesthesia catheters, or when dispensing and administering intravenous drugs. (CDC category IB) **A-IV**
44. Assemble sterile equipment and solutions immediately prior to use. **A-IV**
45. a. Handle tissue gently, maintain effective hemostasis, minimize devitalized tissue and foreign bodies (i.e., sutures, charred tissues, necrotic debris) and eradicate dead space at the surgical site. (CDC category IB) **A-IV**
b. Animal and clinical data suggest that maintenance of intraoperative normothermia will reduce surgical site infections for selected procedures in adults. **A-I** ^{33 34 35 36 37 38}
c. The perioperative use of high inspired concentrations of oxygen and/or induction of mild hypercarbia intraoperatively to prevent surgical site infections are unresolved issues. **UI** ^{39 40}
^{41 42 43 44 45}
46. Use delayed primary skin closure or leave an incision open to heal by second intention if the surgeon considers the surgical site to be heavily contaminated (e.g., Class III and Class IV). (CDC category IB) **B-IV**
47. If drainage is necessary, use a closed suction drain. Place a drain through a separate incision distant from the operative incision, if feasible. Remove the drain as soon as possible. (CDC category IB) **B-IV**

C. Postoperative Care

48. Protect with a sterile dressing for 24 to 48 hours postoperatively an incision that has been closed primarily. *(CDC category IB)* **A-IV**
49. Perform hand hygiene before and after dressing changes and any contact with the surgical site. *(CDC category IB)* **A-IV**
50. When an incision dressing must be changed, use sterile technique. *(CDC category II)* **A-IV**
51. Educate the patient and family regarding proper incision care, symptoms of SSI, and the need to report such symptoms. *(CDC category II)* **A-IV**
52. No recommendation to cover an incision closed primarily beyond 48 hours, nor on the appropriate time to shower or bathe with an uncovered incision. *(CDC category UI)* **UI**
53. For reconstructive procedures involving the use of tissue expanders that require serial inflation with saline, adhere to standards of aseptic technique, including performance of proper hand-hygiene procedures either by washing hands with conventional antiseptic-containing soap and water or with waterless alcohol-based gels or foams, use of clean gloves, and disinfection of the injection site with a skin antiseptic agent prior to saline instillation. **A-IV**

¹ Tanner, J., D. Woodings, et al. (2006). Preoperative hair removal to reduce surgical site infection. *Cochrane Database Syst Rev*(2): CD004122.

² Niel-Weise, B. S., J. C. Wille, et al. (2005). Hair removal policies in clean surgery: systematic review of randomized, controlled trials. *Infect Control Hosp Epidemiol* 26(12): 923-8

³ Vriesendorp, T. M., Q. J. Morelis, et al. (2004). Early post-operative glucose levels are an independent risk factor for infection after peripheral vascular surgery. A retrospective study. *Eur J Vasc Endovasc Surg* 28(5): 520-5.

⁴ van den Berghe, G., P. Wouters, et al. (2001). Intensive insulin therapy in the critically ill patients. *N Engl J Med* 345(19): 1359-67.

⁵ Grey, N. J. and G. A. Perdrizet (2004). Reduction of nosocomial infections in the surgical intensive-care unit by strict glycemic control. *Endocr Pract* 10 Suppl 2: 46-52.

⁶ Collier, B., J. Diaz, Jr., et al. (2005). The impact of a normoglycemic management protocol on clinical outcomes in the trauma intensive care unit. *JPEN J Parenter Enteral Nutr* 29(5): 353-8; discussion 359.

⁷ Lorenz, R. A., R. M. Lorenz, et al. (2005). Perioperative blood glucose control during adult coronary artery bypass surgery. *AORN J* 81(1): 126-44, 147-50; quiz 151-4.

⁸ Gandhi, G. Y., G. A. Nuttall, et al. (2007). Intensive intraoperative insulin therapy versus conventional glucose management during cardiac surgery: a randomized trial. *Ann Intern Med* 146(4): 233-43.

⁹ Webster, J. and S. Osborne (2007). Preoperative bathing or showering with skin antiseptics to prevent surgical site infection. *Cochrane Database Syst Rev* (2): CD004985.

¹⁰ Darouiche RO, Wall MJ, Itani KM, Otterson MF, Webb AL, Carrick MM, Miller HJ, Awad SS, Crosby CT, Mosier MC, AlSharif, A, Berger DH. Chlorhexidine-alcohol versus povidone-iodine for surgical site antisepsis. *N Engl J Med* 2010;362;18-26.

-
- ¹¹ Perl TM, Cullen JJ, Wenzel RP, et al. (2002). Intranasal mupirocin to prevent postoperative *Staphylococcus aureus* infections. *N Engl J Med* 346(24):1871-7.
- ¹² Kallen, A. J., C. T. Wilson, et al. (2005). Perioperative intranasal mupirocin for the prevention of surgical-site infections: systematic review of the literature and meta-analysis. *Infect Control Hosp Epidemiol* 26(12): 916-22.
- ¹³ Kalmeijer, M. D., H. Coertjens, et al. (2002). Surgical site infections in orthopedic surgery: the effect of mupirocin nasal ointment in a double-blind, randomized, placebo-controlled study. *Clin Infect Dis* 35(4): 353-8.
- ¹⁴ Wilcox MK, Hall J, Pike H, et al. Use of perioperative mupirocin to prevent methicillin-resistant *Staphylococcus aureus* (MRSA) orthopedic surgical site infections. *J Hosp Infect* 2003;54:196-201.
- ¹⁵ Kim DH, Spencer M, Davidson SM, Li L, Shaw JD, Gulczynski D, Hunter DJ, Martha JF, Miley GB, Parazin SJ, Dejoie P, Richmond JC. Institutional prescreening for detection and eradication of methicillin-resistant *Staphylococcus aureus* in patients undergoing elective orthopaedic surgery. *J Bone Joint Surg Am* 2010;92:1820-6.
- ¹⁶ Lonneke GM, Bode MD, Kluytmans JAJW, Wertheim HFL, Bogaers D, Vandenbroucke-Grauls CMJE, Roosendaal R, Troelstra A, Bos ATA, Voss A, van der Tweel I, van Belkum A, Verbrugh HA, Voss MC. Preventing surgical-site infections in nasal carriers of *Staphylococcus aureus*. *N Engl J Med* 2010;362:9-17.
- ¹⁷ Association of Operating Room Nurses. (2007). Standards. Recommended Practices, and Guidelines, Denver, CO: AORN, Inc.
- ¹⁸ Bratzler, D. W. and D. R. Hunt (2006). The surgical infection prevention and surgical care improvement projects: national initiatives to improve outcomes for patients having surgery. *Clin Infect Dis* 43(3): 322-30.
- ¹⁹ Bratzler DW, Houck PM. (2004). Antimicrobial prophylaxis for surgery: an advisory statement from the National Surgical Infection Prevention Project. *Clin Infect Dis* 38(12):1706-15.
- ²⁰ Platt R, Zaleznik DF, Hopkins CC, et al. Perioperative antibiotic prophylaxis for herniorrhaphy and breast surgery. *N Engl J Med* 1990;322:153-60.
- ²¹ Dellinger EP, Hausmann SM, Bratzler DW, et al. (2005). Hospitals collaborate to decrease surgical site infections. *Am J Surg* 1990 (1):9-15.
- ²² Institute for Healthcare Improvement. A resource from the Institute of Healthcare Improvement. [Internet] Available from: <http://www.ihc.org> ; accessed 5/1/2007.
- ²³ ASHP Therapeutic Guidelines on Antimicrobial Prophylaxis in Surgery. (1999). American Society of Health-System Pharmacists. *Am J Health Syst Pharm* 56(18):1839-88.
- ²⁴ (2006). Antimicrobial prophylaxis for surgery. *Treat Guidel Med Lett* 4(52): 83-8.
- ²⁵ Tejirian T, DiFronzo A, Haigh PI. Antibiotic prophylaxis for preventing wound infection after breast surgery: A systematic review and metaanalysis. *J Am Coll Surg* 2006;203:729-734.
- ²⁶ Falagas ME, Karageogopoulos DE. Adjustment of dosing of antimicrobial agents or bodyweight in adults. *Lancet* 2010;375:248-51.

-
- ²⁷ Pai MP, Bearden DI. Antimicrobial dosing considerations in obese adult patients. Insights from the Society of Infectious Diseases Pharmacists. *Pharmacotherapy* 2007;27(8):1081-91.
- ²⁸ Anaya DA, Dellinger EP. The obese surgical patient: a susceptible host for infection. *Surg Infect (Larchmt)* 2006;7(5):473-80.
- ²⁹ Steinberg JP, Braun BI, Hellinger WC, et al. Timing of antimicrobial prophylaxis and the risk of surgical site infections: results from the Trial to Reduce Antimicrobial Prophylaxis Errors. *Ann Surg* 2009;250:10-16.
- ³⁰ Scher KS. Studies on the duration of antibiotic administration for surgical prophylaxis. *Am Surg* 1997;63:59-62.
- ³¹ Zalenitsky SA, Ariano RE, Harding GKM, Silverman RE. Antibiotic pharmacodynamics in surgical prophylaxis: an association between intraoperative antibiotic concentrations and efficacy. *Antimicrob Agents Chemother* 2002;46(9):3026-30.
- ³² Facility Guidelines Institute. Guidelines for design and construction of health care facilities. 2010 Edition. Chicago: American Society of Healthcare Engineering of the American Hospital Association. Available from: <http://www.fgiguideelines.org>. Accessed January 25, 2010.
- ³³ Flores-Maldonado, A., C. E. Medina-Escobedo, et al. (2001). Mild perioperative hypothermia and the risk of wound infection. *Arch Med Res* 32(3): 227-31.
- ³⁴ Leaper, D. (2006). Effects of local and systemic warming on postoperative infections. *Surg Infect (Larchmt)* 7 Suppl 2: S101-3.
- ³⁵ Scott, E. M. and R. Buckland (2006). A systematic review of intraoperative warming to prevent postoperative complications. *AORN J* 83(5): 1090-104, 1107-13.
- ³⁶ Melling AC, Ali B, Scott EM, Leaper DJ. (2002). Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomised controlled trial. *Lancet*. 2001 Sep 15;358(9285):876-80. Erratum in: *Lancet* Mar 9;359(9309):896.
- ³⁷ Kurz A, Sessler DI, Lenhardt R. (1996). Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. Study of Wound Infection and Temperature Group. *N Engl J Med* 334(19):1209-15.
- ³⁸ Barone JE, Tucker JB, Cecere J, et al. Hypothermia does not result in more complications after colon surgery. *Ann Surg* 1999;65:356-359.
- ³⁹ Greif R, Akca O, Horn EP, Kurz A, Sessler DI. Supplemental perioperative oxygen to reduce the incidence of surgical-wound infection. Outcomes Research Group. *N Engl J Med* 2000;342(3):161-7.
- ⁴⁰ Pryor KO, Fahey TJ, 3rd, Lien CA, Goldstein PA. Surgical site infection and the routine use of perioperative hyperoxia in a general surgical population: a randomized controlled trial. *Jama* 2004;291(1):79-87.
- ⁴¹ Belda FJ, Aguilera L, Garcia de la Asuncion J, et al. Supplemental perioperative oxygen and the risk of surgical wound infection: a randomized controlled trial. *Jama* 2005;294(16):2035-42.

-
- ⁴² Mayzler O, Weksler N, Domchik S, Klein M, Mizrahi S, Gurman GM. Does supplemental perioperative oxygen administration reduce the incidence of wound infection in elective colorectal surgery? *Minerva Anestesiol* 2005;71(1-2):21-5.
- ⁴³ Myles PS, Leslie K, Chan MT, et al. Avoidance of nitrous oxide for patients undergoing major surgery: a randomized controlled trial. *Anesthesiology* 2007;107(2):221-31.
- ⁴⁴ Meyhoff CS, Wetterslev J, Jorgensen LN, et al. Effect of high perioperative oxygen fraction on surgical site infection and pulmonary complications after abdominal surgery: the PROXI randomized clinical trial. *Jama* 2009;302(14):1543-50.
- ⁴⁵ Qadan M, Akca O, Mahid SS, Hornung CA, Polk HC, Jr. Perioperative supplemental oxygen therapy and surgical site infection: a meta-analysis of randomized controlled trials. *Arch Surg* 2009;144(4):359-66.