Development of Standardized Clinical Assessment and Management Plans (SCAMPs) in Plastic and Reconstructive Surgery

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Background: With rising cost of healthcare, there is an urgent need for developing effective and economical streamlined care. In clinical situations with limited data or conflicting evidence-based data, there is significant institutional and individual practice variation. Quality improvement with the use of Standardized Clinical Assessment and Management Plans (SCAMPs) might be beneficial in such scenarios. The SCAMPs method has never before been reported to be utilized in plastic surgery.

Methods: The topic of immediate breast reconstruction was identified as a possible SCAMPs project. The initial stages of SCAMPs development, including planning and implementation, were entered. The SCAMP Champion, along with the SCAMPs support team, developed targeted data statements. The SCAMP was then written and a decision-tree algorithm was built. Buy-in was obtained from the Division of Plastic Surgery and a SCAMPs data form was generated to collect data.

Results: Decisions pertaining to "immediate implant-based breast reconstruction" were approved as an acceptable topic for SCAMPs development. Nine targeted data statements were made based on the clinical decision points within the SCAMP. The SCAMP algorithm, and the SDF, required multiple revisions. Ultimately, the SCAMP was effectively implemented with multiple iterations in data collection.

Conclusions: Full execution of the SCAMP may allow better-defined selection criteria for this complex patient population. Deviations from the SCAMP may allow for improvement of the SCAMP and facilitate consensus within the Division. Iterative and adaptive quality improvement utilizing SCAMPs creates an opportunity to reduce cost by improving knowledge about best practice. *(Plast Reconstr Surg Glob Open 2015;3:e510; doi: 10.1097/ GOX.0000000000000504; Published online 9 September 2015.)*

The healthcare budget has outpaced the economic growth for multiple decades.[1,2] The percentage of Gross Domestic Product allocated to healthcare has been increasing at an alarming rate and is expected to exceed 20% of US Gross Domestic Product by 2018.[3] Medicine is faced with the challenge of controlling increasing costs while being able to maintain safe and high-quality standards of care. To achieve this balance while avoiding other alternatives such as reimbursement reduction, it becomes imperative to ensure that care delivered is appropriate and unnecessary care is avoided. One way to achieve these goals is to have well-established practice guidelines, backed by objective data, for different clinical situations. Standardized practice

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guidelines (SPGs) may also help in effective communication between the patient and the healthcare providers and may be the key to provide high-quality care while maintaining financial viability.

However, clear and objective data—the lynchpin of most SPGs—is often lacking. In a study where 10 cardiologists at Boston Children's Hospital were shadowed, every clinical decision was recorded and classified by a team of independent observers (Table 1).[4] Surprisingly, 37.1% (441 of 1188) of the decisions were made solely on experience or anecdotal evidence, whereas another 14.7% of the decisions were made arbitrarily or based on instincts. Less than 20% of decisions were made based on the data from research studies. The authors of this study made clear that the physicians studied were academically accomplished and very knowledgeable about the evidence base for pediatric cardiology. This lack of evidence base makes establishing standardized guidelines difficult and could result in significant variability in treatment protocols between different healthcare providers.

Most SPGs that have been developed focus on common medical conditions such as chronic wounds. It is difficult to obtain strong evidence for uncommon medical situations due to lack of powered data.[5–8] Furthermore, SPGs may be difficult to create even in more common conditions or procedures, as high-quality evidence is often lacking or studies may conflict. An example is hypertension (cited in JNC 8) in which 5 of 9 recommendations in a recent guideline revision are based on expert consensus, not high-quality evidence. Specialities such as plastic surgery or congenital heart surgery include a plethora of rare and diverse medical situations. These situations are characterized by both institutional and individual practice discrepancies.[9–12] Similarly, even though there are SPGs from American Society of Plastic Surgeons (ASPS) about the broad topic of breast reconstruction with expanders and implants, there is limited high-quality evidence, making it difficult to produce strong recommenda-

tions.[13,14] Based on the ASPS guidelines, only level III evidence is available for the use of acellular dermal matrix (ADM) during reconstruction and surgeons are expected to evaluate each case individually.[13,14] Also, there is variable evidence regarding the association between postoperative complications and timing of postmastectomy implant breast reconstruction. Absence of strong evidence and lack of society recommendations allows for not only practice variation, but also vulnerability to poor quality of care. The Standardized Clinical Assessment and Management Plan (SCAMP) model was developed to provide standardized care for such medical conditions where evidence was not conclusive.[15,16] Because the SCAMP method is a relatively new concept and has not been implemented in the field of plastic and reconstructive surgery, the goal of this study was to determine the feasibility of SCAMPs. In this manuscript, we investigate the development and implementation of a SCAMP concept in the field of plastic surgery, specifically in immediate breast reconstruction utilizing implants or tissue expanders.

METHODS

In 2011, Brigham and Women's Hospital launched a quality initiative revolving around the development of SCAMPs. An application was submitted by the first author on the topic of implant-based breast reconstruction. Particular areas of interest were highlighted, which were applicable to the SCAMP process. After Brigham and Women's Hospital SCAMPs Executive Committee review, the breast reconstruction application was chosen as one of the first 2 SCAMPs to be performed at our institution. The first author was selected as the SCAMP Champion, commonly the clinical expert who drives the project. The different stages of SCAMPs include the following: (1) Planning, (2) Implementation, (3) Analysis, and (4) Iteration (Fig. 1). After selection of the breast reconstruction SCAMP, the planning stage was entered. First, background research was performed and all available evidence relevant to immediate implant-based breast reconstruction was collected. A clinical background article was written to guide the SCAMP team during SCAMP development. Clinical "hypotheses," or target data statements (TDS), were generated based on the currently available data and the clinical expertise of the SCAMP Champion. TDS were specific to issues surrounding immediate breast reconstruction with tissue expanders or implants that were applicable to further investigation. The goal of the TDS was to target data collection to those questions that would allow the SCAMP pathway to be evaluated and improved upon. The SCAMP Cham-

Table 1. Analysis of Clinical Decision Making among 10 Pediatric Cardiologists at Boston Children's Hospital (N = 1188)

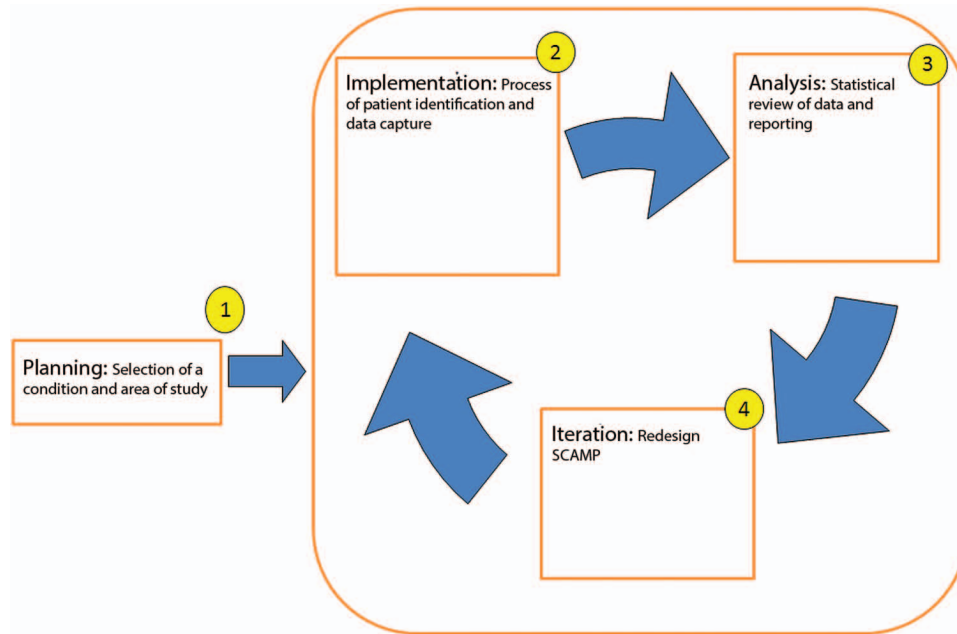|		
Experience or anecdote	441	37.1%
Arbitrary or instinct	175	14.7%
Trained to do it	173	14.6%
First principles	146	12.3%
General research study	146	12.3%
Limited research Study	61	5.1%
Specific research study	34	2.9%
Parental preference	6	0.5%
For research	4	0.3%
Avoid a lawsuit	2	0.2%

Fig. 1. Flowchart demonstrating different steps of SCAMPs.

pion worked closely with the SCAMP team and other faculty members of the Division of Plastic Surgery to reach relative consensus on the TDS.

The next step in the planning stage involves creating an algorithm outlining the proposed standardized clinical steps for the area of the study. Based on the algorithm, a SCAMPs data form (SDF) is generated to allow for real-time data collection, at well-defined points in the clinical workflow. Finally, buy-in is obtained by as many eligible surgeons as possible, hopefully the entire staff.

In the implementation stage, data coordinators ensure that physicians see the SDFs at the point of care and record their decision-making process and reasons for deviations. The process of implementation was closely assessed as rollout commenced.

RESULTS

Our areas of interest included 3 important procedures related to immediate implant-based reconstruction. First, the use of ADM in breast reconstruction is a controversial topic within the literature, with conflicting reports on risk or benefit.[13,14] In addition, it is costly, and therefore, its use should be justified. With lack of concrete SPGs by ASPS regarding the usage of ADM, this was targeted as an excellent area to investigate utilizing a SCAMP. Second, nipple-sparing mastectomy was relatively new to our institution, with no clear consensus on its most appropriate use. We therefore focused part of the SCAMP algorithm on the decision to use this newer procedure instead of the traditional skin-sparing

mastectomy. Our goal was to objectively characterize the patient cohort who would benefit from nipple-sparing mastectomies. Our third area of interest was related to immediate implant breast reconstruction versus tissue expander-to-implant approaches. Permanent implant methods involve a single-stage operation as opposed to initial use of a tissue expander, which requires at least 2 operations and multiple clinical visits for expander filling. Through our SCAMP, we hoped to characterize the patients who would be better suited for permanent implants.

The objectives of these SCAMPs included the following:

Identify patient populations in which above procedures are beneficial.
Understand the factors (skin integrity and risk factors) that may impact the plastic surgeon's decision.
Standardize practice and ultimately improve quality and patient outcomes.
Measure patient satisfaction through Breast Q.

TDSs generated based on the areas of interest related to immediate implant- or expander-based breast reconstruction included the following:

Skin-sparing versus Nipple-sparing Mastectomies
Nipple-sparing mastectomies will have the best outcomes* in patients with mild ptosis (Grade I or mild Grade II), good skin quality (no stretch marks, good elasticity and thickness), and no high-risk factors (history of radiation, smoking, body mass index >40, diabetes).

Nipple-sparing procedures in these patients will result fewer postoperation visits, fewer total operations, and increased patient satisfaction (as measured by Breast Q).

ADM versus No ADM

Use of ADM will result in fewer office expansions and visits, an acceptable increase in rates of seroma and infection in comparison to surgeries without ADM.

Use of ADM will not increase the risk for explantation.

Use of ADM will decrease risk for capsular contracture.

Use of ADM will have best outcomes* for all patients except those with small (A cup) breasts undergoing skin sparing mastectomy (SSM).

Patients with small (A cup) breasts undergoing SSM and no ADM placement will have similar rates of office visits and expansions in comparison to surgeries in which ADM was not used.

Permanent Implant versus Tissue Expanders

Single-stage implant will result in fewer postoperation visits, fewer total operations, and increased patient satisfaction (as measured by the Breast Q)

Single-stage implant will have best outcomes (measured as less post operative complications and increased patient satisfaction as measured by Breast Q) in patients who do not want a major change in breast size (in nipple-sparing surgeries, this means maintaining the same cup size, whereas in skin-sparing surgeries, this means reducing brest size by approximately 1 cup size)

Next, an algorithm for the implant-based breast reconstruction patients was designed by the SCAMP Champion (**See Supplemental Digital Content 1**, which displays a pathway for "immediate implant-based reconstruction" SCAMPs, http://links.lww.com/PRSGO/A128) The algorithm was based on the available literature and the clinical experience of the SCAMP Champion. Using the algorithm results, the SCAMP management team identified points of required data entry and designed a SDF to collect initial data at the first-encounter office consult with the plastic surgeon (**See Supplemental Digital Content 2**, which displays a SCAMPs data form for "immediate implant-based reconstruction" SCAMPs. http://links.lww.com/PRSGO/A129). An effort was made to minimize surgeon impact, in an attempt to improve compliance by decreasing disruption in workflow. Surgeons marked simple checkboxes and recorded deviations in the appropriate locations. No further surgeon input was required, except if the final operation deviated from the preoperative plan. In this case, the

SCAMP management team emailed the surgeon to request a reason for deviation. Chart reviews were performed by the SCAMP management team to clarify operative procedure and track postoperative data of interest. Additionally, the Breast Q was used for patient satisfaction assessment.

In preparation for rollout, the proposed SCAMP was circulated among the Division to elicit comments or suggestions. The entire Division was requested to participate, even (and especially) if their particular clinical practice did not parallel the proposed SCAMP algorithm. Once "buy-in" was obtained by all faculty members, the SCAMP was implemented within the Division. Every patient seeking immediate breast reconstruction with either tissue expanders or implants was entered into the SCAMP. Historically, our Division collectively operates on approximately 250 patients per year for immediate expander/implant reconstruction; therefore, we projected a rapid accumulation of relevant data. Several problems were identified during the initial implementation phase. First, the original SDF was confusing to some. The SDF was revised for clarification and a laminated copy of the SCAMP algorithm was provided to each clinic location for surgeon reference. Next, compliance with initiating the Breast Q was low. High-level administrative analysis revealed extreme differences in individual surgeon practices in regard to preappointment paperwork requirements for patients. For example, some practices sent packets of information to patients in the mail in preparation for their appointment. There was hesitation to increase the paperwork burden on patients in this case by adding the Breast Q preoperative questionnaire. In general, we found it inappropriate to administer the Breast Q in the general patient waiting room, as some questions were very personal and could elicit an emotional response. Asking patients to fill out the lengthy survey once placed in an exam room gave them more privacy, but interrupted clinic work flow. Finally, sending the Breast Q home with patients resulted in poor compliance as it was often forgotten. Fortuitously, a research study was initiated at our institution several months after SCAMP implementation that collected Breast Q data for all breast reconstruction patients. We were able to dovetail the SCAMP project with the new research study and successfully access Breast Q data for all patients.

The analysis and iteration phases of the SCAMP will be performed after 6–12 months of data collection. The analysis will focus on the TDS, adherence to the treatment algorithm, and the clinical and cost effectiveness of the SCAMP recommendations. The data generated from analysis will be used to modify

the SCAMPs pathway if needed and continue the iterative process of data collection and analysis to achieve standardization in practice.

DISCUSSION

As we enter into the era of the Affordable Care Act, healthcare is more than ever under the microscope to provide quality-driven affordable care for patients. Common efforts to obtain this goal include development of SPGs and consideration of systematic reviews. SPGs for most medical and surgical specialties are developed by their respective national societies. SPGs have been shown to reduce to the variability between healthcare providers and cut down the costs and healthcare resource utilization in a variety of medical conditions.[17–21] They have also been successfully utilized in reducing the duration of hospitalization after surgery and the cost of postoperative care.[22,23] In general, SPGs can improve quality of care. However, SPGs are not without limitations. They tend to focus on common medical conditions with solid evidence, with a goal to standardize care. In a specialty such as plastic surgery, there is an abundance of rare and/or diverse medical situations that are characterized by both institutional and individual practice variation.[9–12] In fact, the ASPS evidence-based guidelines for breast reconstruction with expanders and implants finds no Level I evidence on the subject matter. Due to the lack of robust evidence, there are only 2 recommendations labeled "Strong Recommendation." The majority of the ASPS recommendations (10 of 18) for this topic are labeled "Option" with inconsistent or no empirical evidence.[13] The lack of definitive guidelines necessitates the need to provide alternative options for such situations.

Systematic reviews are also utilized by healthcare professionals to practice evidence-based medicine. They provide a critical assessment of the currently available literature addressing a particular clinical problem. However, a significant limitation of systematic reviews is that the evidence collected for the review becomes quickly outdated, or even found to be incorrect at a later date.[24,25] A study reviewing 100 metaanalyses indexed in the American College of Physicians (ACP) journal club from 1995–2005 found that significant new evidence was already available for about 7% of the reviews at the time of publication and became available for 23% of the reviews within 2 years.[24] Lag time in the publication process can negatively affect the usefulness of systemic reviews.

The SCAMPs model is ideally suited for medical conditions in which the management practice is uncertain and there is a room to improve clinical outcomes. There can be wide practice-pattern variation in such scenarios due to the lack of SPGs because of limited evidence-based data. Breast reconstruction with implants or expanders is a prime example of this. A fundamental principle in SCAMPs is that there is no "best practice" and the algorithm can be revised every 6–12 months based on data analysis. SPGs, in comparison, are usually only updated every few years. Data generation does not take multiple years and hundreds or thousands of patients, which is most common in the randomized controlled trials, which form the backbone of most SPGs. The SCAMPs method is a disrupter in the flexibility it affords to achieve rapid iterative care plans. The SCAMPs process accepts that no data are perfect and tries to draw as much information from these data as possible. This is in contrast to systematic reviews, which often discount unsatisfactory data.

In addition, SPGs consider deviations to be incorrect, whereas in SCAMPs deviations are not only encouraged, but are also critical for generation of an ideal SCAMP. The goal of SPGs is to standardize practice by generating preset algorithm based on evidence-based data, which tend to get outdated rather quickly. In contrast, the goal of SCAMPs is to standardize practice by involving all the Divisions' physicians who learn from each other's practice. SPGs limitations that can be addressed by SCAMPs are summarized in Table 2.

Conceptually, SCAMPs can also reduce the financial burden associated with condition management by standardizing practice around decision points involving expensive tests and/or treatments. Use of SCAMPs for pediatric chest pain utilizing several diagnostic tests including echocardiograms, exercise stress test (ESTs), and outpatient rhythm monitors is estimated to cut the financial burden by 20% without negatively affecting the patient care.[25] Similar principles can be applied in the area of implant-based breast reconstruction. ADM use is an additional cost, with inconsistent reports in the literature regarding risks and benefits.

Table 2. Comparison of Standardized Practice Guidelines (SPGs) vs Standardized Clinical Assessment and Management Plans (SCAMPs)

SPGs	SCAMPs
Developed by national societies	Developed by provider
Updated every few years	Updated twice annually (provided sufficient patient volume)
Focus on common conditions with very solid evidence	Focus on any condition, even without great evidence
Deviations considered incorrect	Deviations encouraged
Goal is to standardize practice	Goal is to standardize and learn

Also, costs associated with a single-stage (straight to implant) approach versus the multiple surgery approach of expander to implants can be explored.

CONCLUSIONS

This study reports the novel development of a SCAMP in the field of plastic surgery, specifically focusing on the controversial subtopics within the very common approach of implant-based reconstruction. The goal of this article is not to report on the final outcome of the SCAMPs pathway, but to demonstrate its feasibility and appropriateness in our specialty. This study does not undermine the purpose of SPGs, but proposes to establish the complementary role of SCAMPs in uncommon clinical scenarios with limited evidence or potential for cutting costs. Future steps include 6–12-month data analysis with possible SCAMP redesign and reimplementation. Implementation, analysis, and iteration will continue in a cyclic fashion until treatment for implant-based reconstruction is optimized in our institution.

One of the limitations of our study is implementation of SCAMPs at a single institution. Based on our initial success, we hope to include sister institutions to improve our outreach and provide standardized care.

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