Evidence-based Medicine and Data Sharing in Outpatient Plastic Surgery

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KEYWORDS

• Evidence-based medicine • Data sharing • Outpatient surgery • Plastic surgery • Patient outcomes • EBM implementation

KEY POINTS

- Plastic surgery organizations have put forth initiatives to improve EBM skills among plastic surgeons.
- Small steps toward understanding and mastering the practice increase the level of expertise, improve outcomes for patients, and raise the bar for patient safety.
- Openness toward data sharing and better standards for implementing it strengthen the evidence base and lead to better health care quality and optimal patient outcomes.
- Modern EBM is composed of five core steps: (1) assessing clinical practice to identify an important patient or policy problem; (2) asking clinical questions that are related to the problem and constructed to facilitate a sufficient literature search; (3) acquiring the best available evidence to answer the clinical question; (4) appraising the validity, importance, and clinical use of the evidence; and (5) applying evidence that is relevant to individual patients and aligned with their preferences and values.

INTRODUCTION

To become a plastic and reconstructive surgeon requires years of graduated responsibility in a structured residency training program. During this training period prospective surgeons gain technical expertise to perform surgical procedures and manage patient care through careful observation of their mentors and increasing responsibility, much like an apprenticeship.[1] Although the mentors are incredibly skilled and experts in their field, relying on expert opinion to make treatment decisions is no longer sufficient in the realm of evidence-based medicine (EBM). As pressures from regulators and payers are increasing, the performance of surgeons is being scrutinized like never before. Treatment decisions that were once based on various forms of evidence, such as years of surgical practice, successes with previous patients, and information from the surgical literature, must now be supported by strong clinical evidence to be considered acceptable by the wider health care community.[1]

Plastic surgeons must be dedicated to patient safety and quality improvement in all areas of practice. The use of EBM is particularly important for outpatient surgery, because approximately

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80% of surgeries in the United States are performed as outpatient procedures[2] and many ambulatory surgery facilities are unaccredited and in many states uninspected, with no regulatory oversight.[3] Efforts are underway to promote accreditation of ambulatory surgery centers,[3] but learning EBM and implementing its principles are also critical for improving quality and patient outcomes in the outpatient setting.

HISTORY AND PRINCIPLES OF EBM

EBM is the conscientious, explicit, and judicious use of current best evidence, combined with individual clinical expertise and patient preferences and values, in making decisions about the care of individual patients.[4] Rudimentary accounts of evidence-based practice date back to ancient times[5,6]; however, the term "evidence-based medicine" did not exist until the early 1990s, when it was first published in the ACP Journal Club[7] and later introduced to the wider medical community by the Evidence-Based Medicine Working Group.[8] Initially, the concept of EBM was met with much criticism, because it incorrectly implied that the practice of medicine was unscientific. Over time, health care professionals began to understand that EBM was a framework and cultural standard for finding and applying the best evidence to guide treatment decisions.[9]

Although the acceptance and practice of EBM has increased since the early 1990s, audits of medical and surgical procedures have revealed that low levels of evidence are still guiding treatment decisions.[10–12] Importantly, these audits were conducted at single institutions shortly after EBM emerged, so it is unclear if the findings are representative of most health care facilities today. Nevertheless, there are always be cases for which little to no evidence is available, and clinicians need to rely on their best judgment and best available evidence at the time, but more work is needed to increase awareness of EBM and promote better research practices to enhance the evidence base and ensure that most treatment decisions are based on sound evidence.

Unfortunately, even when evidence is available, the research findings have the potential to be biased. This bias, or systematic error, is a reproducible error in study design or conduct that leads to systematic deviations from the underlying truth.[9,13] Basing treatment decisions on biased information or inadequately tested theories can have devastating effects on patient outcomes.[14] Therefore, clinicians need an understanding of EBM principles to help identify the best evidence to guide practice.

Modern EBM is composed of five core steps: (1) assessing clinical practice to identify an important patient or policy problem; (2) asking clinical questions that are related to the problem and constructed to facilitate a sufficient literature search; (3) acquiring the best available evidence to answer the clinical question; (4) appraising the validity, importance, and clinical use of the evidence; and (5) applying evidence that is relevant to individual patients and aligned with their preferences and values.[9,15] **Table 1** provides an overview of these steps and helpful methods for accomplishing each step, which are also described herein.

After a problem has been identified, developing a good clinical question facilitates a successful literature search. Clinical questions can be about treatment; harm; prognosis; diagnosis; or cost-effectiveness (economic analysis). The PICO (*P*opulation, *I*ntervention, *C*omparison, *O*utcome) method is commonly used to develop clinical questions.[9,15] An answerable clinical question in outpatient plastic surgery may be: "For women with breast hypertrophy, does breast reduction compared with physical therapy result in better health-related quality of life?," where the patient population is women with breast hypertrophy, the intervention is breast reduction, the comparison intervention is physical therapy, and the outcome is health-related quality of life.

Finding the evidence to answer the clinical question involves several steps. First is to define the literature search strategy. The STARLITE (*S*ampling strategy, *T*ype of study, *A*pproaches, *L*imits, *I*nclusion/exclusion criteria, *T*erms, and *E*lectronic sources) method is a useful tool for developing a search strategy.[16] The type of clinical question helps to narrow the search to specific types of studies. For example, clinical questions about therapy are best answered with data from randomized controlled trials (RCTs), whereas clinical questions about prognosis are best answered with data from cohort designs. All types of study designs can be included in the search to optimize results, especially when little evidence exists for a particular question or a particular study design is not feasible or ethical; however, searches should aim to identify studies with the highest levels of evidence to best inform clinical decisions. Searching several bibliographic databases, including repositories of gray literature, and hand searching the bibliographies of relevant articles increases the likelihood that the body of evidence that has been collected is comprehensive and represents the underlying truth.

A common misconception in EBM is that the study design alone determines the strength of the evidence. Although RCTs can provide strong evidence, they are not created equal. The results

Table 1
Core steps of EBM and methods for performing each step

Step	Description	Methods
Assess	Recognize, classify, and prioritize important patient or policy problems	Assess problems in individual practice Search review articles and clinical practice guidelines to identify unmet medical needs Discuss areas of interest and potential clinical issues with colleagues Listen to patients to identify unmet needs that are important to patients
Ask	Construct clinical questions that facilitate an efficient search for evidence	Use PICO to develop good clinical questions: identify the patient/population/problem, intervention, comparison, outcomes
Acquire	Gather important and convincing evidence from high-quality repositories of the health literature	Use STARTLITE to develop a search strategy. Identify the: Sampling strategy: all or selected studies Type of study: systematic reviews, RCT, and so forth Approaches: electronic search, hand search, and so forth Limits: English-language articles, humans, age of patients Inclusion and exclusion: criteria for including or excluding studies Terms: search terms (MeSH terms, key words, and so forth) Electronic sources: electronic databases (eg, MEDLINE, CINAHL, Cochrane Library, and so forth)
Appraise	Systematically check best available evidence for indications of validity, importance, and usefulness	Use critical appraisal tools and resources to assess for potential biases: Center for Evidence Based Medicine, http://www.cebm.net/ Users' Guides to the Medical Literature (JAMAevidence), http://jamaevidence.com/ Critical Appraisal Skills Program, http://www.casp-uk.net/ Grading of Recommendations Assessment Development and Evaluation Working Group http://www.gradeworkinggroup.org/index.htm
Apply	Interpret the applicability of evidence to specific problems, given patient preferences and values	Weigh the risks and benefits of the treatment option for each patient Ensure that the treatment option aligns with the patient's values and preferences Develop plans for implementing the evidence in private practice and larger health care facilities (knowledge translation)

of small, poorly designed RCTs can be misleading. Therefore, all types of studies should be appraised to determine their validity, importance, and clinical applicability. Critical appraisal is the process by which the methodologic quality of a study is screened for potential biases. Several critical appraisal tools have been developed to aid clinicians with this process. Importantly, each type of study is evaluated by a specific set of criteria. **Box 1** provides an example of a critical appraisal tool for evaluating an RCT.

If after critical appraisal the study is deemed to be of high quality for the particular study design, it is then assigned a level of evidence according to the clinical question that the study attempted to answer. Numerous rating scales and their iterations have been published over the years; many are based on the first rating scale that was published by the Canadian Task Force[17] and later refined by Sackett[18] and the Center for Evidence Based Medicine.[19] Typically, levels of evidence range from I to V, with I representing the highest

Box 1
Critical appraisal tool for an RCT

Assessment for Selection Bias

- Where patients recruited appropriately?
- Was allocation concealed?
- Were participants randomized appropriately?
- Were treatment groups similar with respect to known and unknown prognostic factors?
- Were confounders addressed?
- Were data complete for at least 80% of participants in each group?
- Were any significant differences found between participants who were lost to follow-up and those who completed follow-up?
- Were participants analyzed in the group to which they were randomized (intention-to-treat)?

Assessment for Intervention Bias

- Was the intervention well described?
- Was the intervention implemented similarly in all participants (ie, could level of surgeon expertise influence how the procedure was performed; were there any protocol deviations)?
- Was the caregiver (eg, surgeon) masked?

Assessment for Measurement Bias

- Were the participants, outcome assessors, and data analysts masked?
- Were outcomes measured similarly and with valid, defined criteria?
- Was follow-up sufficient to detect all outcomes of interest?

Assessment for Type II Error

- Was power sufficient to detect differences for each measured outcome?

level or strongest evidence and V representing the lowest level or weakest evidence. *Plastic and Reconstructive Surgery* has implemented a pyramid system to identify the clinical question and level of evidence of studies published in the journal (**Fig. 1**).[20] The pyramid is located on the first page of each article, providing a prominent visual cue that alerts the reader to the strength of the evidence provided by the study.

After critically appraising each study for a particular clinical question, the collective body of evidence is graded according to its strength in guiding a clinical recommendation. Like rating scales for levels of evidence, a variety of grading scales are available for recommendations. Recommendations are typically graded from A to D, with A representing the strongest recommendation and D representing the weakest recommendation. High levels of evidence often lead to strong clinical recommendations; however, this is not always the case. For example, high-level evidence suggests that continuous anticoagulation therapy reduces the risk of recurrent thrombosis in patients who have had an unprovoked deep vein thrombosis. However, continuous treatment with an anticoagulant also increases the risk of bleeding and is inconvenient for the patient. Therefore, weighing the benefits and risks of continuous anticoagulation therapy for this patient population may result in only a weak to moderate recommendation.[21] **Tables 2** and **3** illustrate the evidence and recommendation scales used by the American Society of Plastic Surgeons and the American Society of Aesthetic Plastic Surgery.[22,23]

Although scales for rating the level of evidence and grading recommendations are largely similar across medical specialties, a universally accepted rating system has yet to be established. The Grading of Recommendations Assessment Development and Evaluation Working Group, an international collaboration of experts in EBM, is focused on addressing concerns with the current grading systems in health care and has developed its own approach to evaluating evidence and recommendations that is gaining acceptance worldwide.[24]

CURRENT IMPLEMENTATION OF EBM

Today, EBM is used in many ways to guide practice. Individual clinicians, guideline developers, and CME providers use EBM to identify and teach best practices. The US Food and Drug Administration and other regulatory agencies worldwide require strong clinical evidence to approve new drugs and devices.[25] With increasing demands to fulfill unmet medical needs, regulatory agencies will likely tighten regulatory requirements regarding evidence. Government and private health plans also use evidence to determine the value and cost effectiveness of therapeutic products and develop reimbursement schedules for such treatments. EBM is the foundation for comparative effectiveness research (CER), which was introduced by the Congressional Budget Office in 2007[26] and later redefined by the Federal Coordinating Council for CER "…to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most

Fig. 1. Levels of evidence pyramid identifying the clinical question and level of evidence (I through V) of studies published in *Plastic and Reconstructive Surgery.* (*Left*) Diagnostic clinical question addressed, with a level of evidence of II. (*Center*) Therapeutic clinical question addressed, with a level of evidence of III. (*Right*) Risk clinical question addressed, with a level of evidence of II. (*From* Sullivan D, Chung KC, Eaves FF, et al. The level of evidence pyramid: indicating levels of evidence in *Plastic and Reconstructive Surgery* articles. Plast Reconstr Surg 2011;128:311–4; with permission.)

effective for which patients under specific circumstances."[27] CER promotes the use of EBM to address practical clinical questions in real-world settings to identify optimal treatments for individual patients. Although RCTs and meta-analyses are still predominant components in CER, other sources of evidence, such as observational studies, registry data, and health-related quality-of-life studies, are considered because they complement randomized studies and contribute to the larger body of evidence that may help to identify important patient needs.

Table 2
Scale for rating the level of evidence of therapeutic studies[a]

Level of Evidence	Qualifying Studies
I	High-quality, multicentered or single-centered, randomized controlled trial with adequate power; or systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies
III	Retrospective cohort or comparative study, case-control study, or systematic review of these studies
IV	Case series with pretest and posttest, or only posttest
V	Expert opinion developed by consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

[a] Scales for rating prognostic and diagnostic studies differ from this scale.

Patient values and preferences are important components of EBM.[9] In 2010, Congress developed the Patient Centered Outcomes Research Institute (PCORI) through the Patient Protection and Affordable Care Act to facilitate comparative clinical effectiveness research. Although developed by Congress, PCORI is an independent organization with a Board of Governors comprised of 21 members who represent all stakeholders. EBM is central to PCORI's goals and is emphasized in its mission statement: "[PCORI] helps people make informed health care decisions—and improves health care delivery and outcomes—by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community."[28] It is unclear how this initiative will change in the coming years, but EBM will almost certainly remain a strong component in health care legislation and regulation moving forward.

EVIDENCE-BASED PLASTIC SURGERY: CHALLENGES AND SOLUTIONS

Plastic surgery organizations, such as the American Society of Plastic Surgeons and American Society of Aesthetic Plastic Surgery, have set forth initiatives to promote awareness of EBM in plastic surgery and to teach its principles to the practicing surgeon[23,29–33]; however, surgeons may be hesitant to adopt EBM practices because of time constraints, limited surgical evidence, and inherent challenges in designing rigorous surgical studies.

Table 3
Scale for grading recommendations

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role
D	Option	Level V: little or no systematic empiric evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit vs harm; patient preference should have a substantial influencing role

Unlike medicine, surgical procedures are often difficult to evaluate with RCTs; according to data from a systematic review on surgical studies, only 40% of the clinical questions could be answered with a randomized study design.[34] As a result, most surgical studies are retrospective case series or reports.[1,13,35,36] Although designing surgical trials may be challenging, attention to good research design may help to improve the surgical evidence base. Surgical trials that are not randomized are subject to selection bias, which occurs when treatment groups are different with respect to known and unknown prognostic factors. If baseline characteristics are not well balanced between the groups, it becomes less clear that any differences in outcomes between the treatment groups are associated with the intervention. Because randomization in surgical studies is not always feasible or ethical, researchers must minimize potential bias in other ways. Inclusion and exclusion criteria can be used to ensure that the study population is comprised of patients with similar characteristics. Another option is matching each patient in one group to a patient in the other group who has similar prognostic factors. Additionally, statistical methods that account for potential confounders (eg, multivariate analyses) should be defined a priori and incorporated into data analysis to determine the effects of known confounders on patient outcomes. Although these strategies can minimize selection bias in the absence of randomization, they are unable to eliminate the potential effects of unknown confounders.[13]

When blinding (or masking) is not incorporated into the study design and individuals involved in the study are aware of the treatment allocation, intervention and measurement biases can occur. In surgical trials, masking of surgeons is usually impossible, but masking of other individuals, such as patients, other health care providers, outcome assessors, and data analysts, should be attempted whenever feasible to minimize potential biases.[13] Surgeon expertise and preferences also can introduce intervention bias into surgical studies. Allowing time for surgeons to master the surgical intervention before initiating the study and using expertise-based RCTs, where patients are randomized to a surgeon instead of a treatment arm, can help to overcome potential biases associated with differential expertise among the investigators.[1,13]

Measurement bias can occur when outcome assessors are not masked to treatment allocation or when outcomes are not well defined or measured with standardized criteria. Therefore, defining clinical end points and outcome measures a priori is extremely important. Objective

outcomes, especially those that are indisputable (eg, mortality), are less likely to introduce measurement bias; however, outcomes in plastic surgery are often subjective (eg, cosmesis, quality of life, or patient satisfaction).[13] Investigators should incorporate objective measures whenever possible. For example, in studies that aim to determine the rate of infection after a surgical procedure, "infection" should be well defined and diagnosed with a standardized set of criteria (eg, Centers for Disease Control and Prevention Surgical Site Infection [SSI])[37] during the study. Efforts are underway to develop validated tools for measuring other outcomes, such as health-related quality of life after plastic surgery.[38]

Determining the minimum amount of follow-up is important for ensuring that all outcomes of interest are detected during the study.[13] Similar to the previous scenario, if SSI is an outcome of interest, then follow-up should be at least 30 days according to the Centers for Disease Control and Prevention's definition of SSIs.[37] Losses to follow-up should also be accounted for in data analysis, because patients who fail to complete follow-up may be different from those who do, and those differences may influence the study results.[13]

Attention must also be paid to other elements of study design, such as determining the required sample size (ie, performing power calculations a priori) and incorporating intention-to-treat analyses to increase validity of study results.[13] Research reporting guidelines are helpful for designing clinical trials and ensuring that methods and results are reported properly. Guidelines for various types of study designs (eg, CONSORT for RCTs) are available on the Web site of the EQUATOR Network.[39]

THE ROLE OF DATA SHARING IN EBM AND ITS IMPORTANCE FOR IMPROVING HEALTH CARE QUALITY AND PATIENT OUTCOMES

Data sharing is particularly critical to the implementation of EBM. Restricted access to research data precludes a thorough evaluation of all evidence for a particular clinical question, potentially leading to reporting bias and erroneous conclusions about therapeutic interventions and other health care issues. Publication bias is a form of reporting bias that occurs when the publication of a study depends on the direction and statistical significance of the study results. For example, studies with positive findings are published more frequently than those with negative findings. An audit of more than 30,000 surgery articles from 12 journals revealed that 74% of the articles reported positive findings, 9% were neutral, and only 17% reported negative findings.[40] Publication bias and other forms of reporting bias (**Table 4**)[41] can threaten the validity of studies that synthesize large amounts of data, such as meta-analyses.[42–44] If access to data is restricted and investigators fail to sufficiently search the gray literature for unpublished data, the results of meta-analyses may be inaccurate. According to a survey of recent meta-analyses of RCTs,

Table 4
Types of reporting bias

Type of Reporting Bias	Definition
Publication bias	The *publication* or *non-publication* of research findings, depending on the nature and direction of the results
Time lag bias	The *rapid* or *delayed* publication of research findings, depending on the nature and direction of the results
Multiple (duplicate) publication bias	The *multiple* or *singular* publication of research findings, depending on the nature and direction of the results
Location bias	The publication of research findings in journals with different *ease of access* or *levels of indexing* in standard databases, depending on the nature and direction of results
Citation bias	The *citation* or *non-citation* of research findings, depending on the nature and direction of the results
Language bias	The publication of research findings *in a particular language*, depending on the nature and direction of the results
Outcome reporting bias	The *selective reporting* of some outcomes but not others, depending on the nature and direction of the results

From Higgins JP, Green S, editors. Cochrane handbook for systematic reviews of interventions version 5.1.0 [updated March 2011]. The Cochrane Collaboration. 2011. Available at: www.cochrane-handbook.org. Accessed October 12, 2012; with permission.

only 29% of the meta-analyses included data from gray literature.[42] In another study in which investigators re-evaluated meta-analyses of drug trials by incorporating unpublished data that were not included in the original meta-analyses, 46% of the re-evaluated meta-analyses showed lower efficacy, 46% showed greater efficacy, and only 7% showed identical efficacy compared with the original meta-analyses.[45] Complete reporting, data sharing, and transparency in research are needed to ensure that the published body of evidence represents the truth.

Several government agencies, organizations, foundations, journal editors, and other entities worldwide are promoting the importance of data sharing for improving health care quality and patient outcomes. In the United States, the Health Information Technology for Economic and Clinical Health Act promotes the use of digital technology to provide health care professionals with critical information to improve the quality of care delivery, reduce errors, and decrease costs and to improve population health by simplifying collection, aggregation, and analysis of anonymized health information.[46] The National Institutes of Health mandated that the results of all studies funded by the National Institutes of Health be made publicly available within 12 months of publishing the final, peer-reviewed manuscript.[47] The Bill and Melinda Gates Foundation published its Global Health Data Access Principles,[48] promoting rapid, global access to health-related data to improve the discovery and development of life-saving interventions.

Although there are many compelling reasons for data sharing, there are also significant concerns. Public access to individual patient data poses a risk to patient confidentiality. Albeit small, the risk of inadvertent publication of personal information exists. Even if data are anonymized, patients could be identified, especially those with rare conditions or diseases. Moreover, universally accepted definitions of "anonymized" or "deidentified" data remain to be established[49]; thus, information that is protected by one entity may not be protected by others. For example, the Health Insurance Portability and Accountability Act in the United States and the Data Protection Act in the United Kingdom have different definitions of personal information and different provisions for protection.[50,51] Another concern surrounding data sharing is that the unrestricted access to full datasets could lead to publication and promotion of misleading information, potentially causing public health scares with devastating consequences (eg, patients discontinuing treatment or refusing vaccination).[52]

Strategies to minimize the risks associated with data sharing are necessary for improving access to data. Guidelines for publishing raw data and developing and using patient registries are available,[49,53] but universally agreed-upon standards are needed to gain greater acceptance by patients and the wider health care community. Studies have found that patients are often willing to share their health data, but remain concerned about the protection and use of their information and their options for sharing the information.[54,55] Allowing patients to select options for sharing their data and developing effective, universally accepted provisions for protecting and using patient data may increase access to data. Increased resources for implementation are also necessary, because activities involved in data sharing may be time intensive and require effective oversight.[46,52] Additionally, sharing negative study results is essential for ensuring that the evidence base is comprehensive and representative of the truth. Academic institutions, journals, and funding agencies should encourage investigators to publish positive and negative study results.[56]

Outcomes for outpatient surgical procedures, collected through the American Association for Accreditation for Ambulatory Surgery Facilities' Internet Based Quality Assurance Program, have been previously reported.[57,58] Although of great value, outcomes alone do not provide complete information about the surgical process. Care delivery can be improved by inclusion of key elements that led to the outcome. A new concept, originating from the work being done by Keyes and colleagues[57,58] in the area of data collection on outpatient surgery, involves the digitalization of the entire surgical process for individual procedures. Beginning with the indications for surgery and following the delivery of care in the preoperative, intraoperative, and postoperative phases, a digital representation of specific aspects of care is integrated with outcomes, which can help identify the root causes for the outcomes, rather than just identifying the outcomes. This digitalization enhances the ability to provide EBM for specific procedures, improving patient care. For example, identifying the key elements potentially responsible for the development of a venous thromboembolism facilitates the decision to provide chemoprophylaxis.

SUMMARY

Acceptance and implementation of EBM has increased in recent years. Plastic surgery organizations have put forth initiatives to improve EBM skills among plastic surgeons. As plastic surgeons

have learned throughout medical school, residency, and their own practices, repetition is the key to mastering skills. EBM is no different. The steps involved in EBM may seem daunting to the busy clinician, but small steps toward understanding and mastering the practice increase the level of expertise, improve outcomes for patients, and raise the bar for patient safety. Designing rigorous surgical studies by incorporating strategies for minimizing bias provides stronger evidence in plastic surgery, and publishing positive and negative findings allows for unbiased analyses of the larger body of evidence. Openness toward data sharing and better standards for implementing it strengthens the evidence base and leads to better health care quality and optimal patient outcomes. Implementing EBM and methods for data sharing in plastic surgery also enhances quality and safety in the outpatient setting.

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