August 8, 2014

The Honorable Ron Wyden
U.S. Senate
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Charles Grassley
U.S. Senate
135 Hart Senate Office Building
Washington, DC 20510

Submitted electronically via data@finance.senate.gov

RE: AANS/CNS Feedback on Enhancing the Availability and Utility of Healthcare Data

Dear Senators Wyden and Grassley,

On behalf of the 4,000 practicing neurosurgeons in the United States, the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) appreciate the opportunity to provide the Senate Finance Committee with input on how to make healthcare data more useful and readily available to the public. The AANS and CNS recognize the potential value of healthcare data. If collected and used appropriately, such data could provide accurate and meaningful information to patients, physicians, and other stakeholders, which can improve quality and lead to more efficient and appropriate care.

Overall, organized neurosurgery supports efforts to increase knowledge about the quality of healthcare and the efficient use of resources in the delivery of healthcare services. We also recognize that greater access to healthcare data will assist with the development and testing of new delivery models and help to transform existing payment systems. However, there is a critical need to safeguard against potential abuses and unintended consequences related to the release of healthcare data that could negatively impact patient outcomes, lead to greater complexity and confusion, and result in false or incorrect accusations about healthcare providers, without due process. As such, we appreciate your continued efforts to engage the physician community on this issue and offer the following responses to your questions.

1. **What data sources should be made more broadly available?**

The AANS and CNS have long promoted the value of clinical data over claims data in providing more accurate and relevant information regarding medical care. While claims data are routinely collected and relatively inexpensive to analyze, they are intended for billing purposes and not for quality reporting or capturing the nuances of clinical care. National specialty societies, including organized neurosurgery, are widely engaged in the development of clinical data registries, which produce more robust data than are available through claims, are audited for completeness and accuracy, include risk adjustment methodologies that appropriately account for patient severity, and benchmarking that makes the most sense for the specialty and their patient populations.
Although there is a clear preference for clinical data, clinical data registries will not reach their full potential of addressing the value conundrum, unless we are able to combine clinical information with cost data and death information from the Social Security Administration. Linking clinical data with resource utilization data will provide a mechanism to risk-adjust both clinical outcomes and resource utilization, thereby allowing us to better assess the value of care provided by neurosurgeons. As such, we continue to urge CMS to make MEDPAR data available on a regular basis to qualified registries. In addition to providing Medicare claims data, it would also be enormously beneficial for registries to have access to the state-reported death data, which is part of the Social Security Death Master File (SSDMF). While we are sensitive to restricting access to the SSDMF so as to “protect” those listed in the file, the AANS and CNS believe that legitimate privacy concerns can be addressed, while also providing qualified registries with access to SSDMF data. Linking clinical registries to the SSDMF allows for the verification of “life status” of patients who otherwise would be lost for follow-up after their treatment, and this longitudinal survival data is vital in assessing the long-term efficacy of many treatments provided by neurosurgeons.

As noted, data generated from clinical data registries are more appropriate for public reporting versus claims data alone. However, the comprehensiveness of clinical data also makes collection and the development and application of statistical analyses more resource-intensive. We therefore urge Congress to continue to promote the value of clinical data collected via registries as you strive to expand public availability of meaningful information. This should include an investment in tools and other resources to assist professional societies with the development and maintenance of registries. It should also include regulatory reforms that ease the burden of data collection for quality improvement purposes, which are discussed below. Finally, Congress also must recognize that clinical data collection efforts vary among specialties. As such, we strongly recommend a scaled approach to the public reporting of such data to give specialties an opportunity to evaluate the value and feasibility of collecting different data elements, to test the accuracy of various analytics, and to develop and test different benchmarks and reporting formats.

2. How, in what form, and for what purposes should this data be conveyed?

If not approached thoughtfully, public release of healthcare data can have unintentional adverse consequences for patients. For example, the release of inadequately adjusted performance data for accountability purposes can result in patient de-selection for individuals at higher-risk for illness due to age, diagnosis, severity of illness, multiple co-morbidities, or economic and cultural characteristics. Furthermore, data presented in complex or even over-simplified formats can result in confusion among both patients and physicians and actually hamper well-informed medical decision-making. Likewise, public release of information in the media or on the Internet, without safeguards and due process, can jeopardize the professional reputations of innocent physicians and threaten their ability to practice medicine. There is a well-documented history of private insurers misusing claims data to profile physicians, deny them reasonable reimbursement, or subject patients to higher out-of-pocket costs.

As member of the Surgical Quality Alliance (SQA), the AANS and CNS recently assisted with the development of the attached report titled, Surgery & Public Reporting: Recommendations for Issuing Public Reports on Surgical Care, which discusses appropriate standards to ensure the accuracy and relevancy of publicly reported data related to surgical care. We urge you to read this report in its entirety, but highlight some key recommendations that Congress, CMS and others should adhere to when advancing the availability and utility of healthcare data:

• All reports should make their methodology publicly available and should include a detailed description of any data used to estimate performance (i.e., the data source), use of statistical risk-adjustment techniques, the selection of performance measures, and how surgical performance
was categorized. Reporting bodies should not use “black box” proprietary measures, which make it impossible to audit the report results.

- Each report should be independently deemed reliable and valid prior to release.
- Reports must be transparent about the observation period for a given quality measure, including the differentiation between long-term follow-up and short-term outcomes.
- Include a statute of limitations within the public report. Outdated reports must be removed from circulation.
- Use proper risk adjustment, as determined by the appropriate specialty society, to ensure ongoing access for patients who are at higher risk of complications and poor outcomes.
- Ensure that specialty societies have an opportunity to provide input regarding recommended physician measures chosen for public reporting and participate on the workgroup or panel selecting measures for the reports.
- Employ standardized reporting formats.
- Provide an opportunity for individual surgeon review and feedback before public reporting. Ensure a proper appeals process, including the process for managing contested reports.
- Conduct pilot tests to determine usefulness and effectiveness of reports.
- Evaluate the extent to which the report fulfills its stated purpose and identify any unintended consequences with special focus on addressing misclassification.
- Public reports should not be used to establish the standard of care or duty of care owed by a health care provider (see discussion below).

It is equally important that the format of data released to the public is easily understandable, relevant, and actionable for both patients and physicians.

3. What reforms would help reduce the unnecessary fragmentation of healthcare data? What reforms would improve the accessibility and usability of healthcare data for consumers, payers, and providers?

With regard to reducing the unnecessary fragmentation of healthcare data, the healthcare industry continues to lack agreement on standards related to interoperability and health information exchange between settings, between electronic health records (EHRs) and between EHRs and registries. Interoperability is integral to gaining a better understanding of where care can be improved, promoting more patient-centric treatment and outcomes, reducing medical errors, and minimizing the cost of healthcare delivery. Although there are many independent interoperability efforts in progress, appropriate government agencies, in consultation with Congress and other stakeholders, should oversee this process to achieve common and consistent platforms, language and definitions, and to promote more robust, nationwide data exchange. The medical profession now finds itself in a cart-before-the-horse situation where it is being asked to achieve a goal (and being held accountable for it) that is not possible to achieve without the adoption of such standards.

To reduce fragmentation of data and improve the accessibility of data, it is also absolutely imperative that Congress address some of the unnecessary regulatory barriers that currently stand in the way of data collection. One area, in particular, that has hindered neurosurgery’s progress in developing a robust clinical data registry are the current regulatory requirements related to informed consent. Because the standards surrounding research and the protection of human subjects are more developed and precise than those related to quality improvement activities, the latter efforts are often subject to the same standards that apply to research. This situation is complicated by a fundamental lack of consistency in local interpretations among institutional review boards (IRBs) of the provisions of the “Common Rule”

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and HIPAA’s privacy requirements as they relate to quality data collected by clinical data registries. Because clinical registries rely on serial evaluation of patient outcomes, the requirement for informed consent undermines quality improvement and can introduce significant selection bias into quality analyses. Simply put, when a requirement for informed consent exists, patients who are willing to give consent often comprise a non-representative subset of the population of interest and result in a data set that may be of little value. In general, unnecessary application of informed consent and other patient authorizations could significantly compromise the validity of data assessments and create significant impediments to generating data of adequate quality to drive practice improvement.

Given these challenges, there is an urgent need for regulatory agencies to establish appropriate standards for quality improvement activities that will both adequately protect patients and not unnecessarily burden quality improvement efforts. Until that guidance arrives, it will be difficult for clinicians to participate in the full spectrum of quality efforts now mandated in the public and private sector. We specifically request that Congress urge the Department of Health and Human Services (HHS) to:

- Require the Office of Human Research Protections (OHRP) and Office of Civil Rights (OCR) to issue guidance that the Common Rule does not apply to the collection and analysis of identifiable patient information for quality improvement purposes where the entities collecting and analyzing the data (such as clinicians and a corresponding clinical data registry) are engaged in standard patient care and are in compliance with all applicable HIPAA requirements. There is no need to apply the Common Rule for data collection activities where HIPAA compliant policies, procedures, and waivers are already in place because the HIPAA Privacy and Security Rules provide the same or greater protection for patient data as the Common Rule.

- Include explicit language in federal guidance to allow for a clear differentiation between “human subjects research” and the processes related to the essential prospective data analyses that are needed to pursue national quality of care objectives. In particular, the generation of new knowledge should be recognized as an expected and desired outcome of healthcare quality improvement projects; the processes related to the generation of such knowledge should therefore be exempt from a requirement for informed consent (assuming that all HIPAA related regulations are adhered to in the course of clinical data collection and analysis).

Ideally, Congress would require the Secretary of HHS to adopt an exception to the Common Rule for cases where registries and others that are collecting identifiable patient data without direct interaction with human subjects and where the privacy and security regulations issued under the Health Insurance Portability and Accountability Act (HIPAA) also apply and are being followed.

In terms of improving the usability of data, there is a great need to ensure that the release of data does not mislead or confuse the public, which could result in inappropriate and potentially harmful healthcare decision-making and contradict the goals of greater transparency. The unprecedented release of Medicare physician payment data in April, for example, revealed more about the limitations of publicly reporting raw data than it did about medical practice. The figures lacked the context needed to distinguish between physicians who are truly abusing the system and those who, appropriately, see a disproportionately large number of Medicare patients, perform a large number of risky or complex procedures, or whose specialty includes high overhead costs. The April release also underscored the need to include narratives or disclaimers alongside such data to better guide interpretation by the public and to give physicians the opportunity to review and correct data before it is shared with the public. In this case, physicians obtained access to the data at the same time the public did, with zero opportunity to review and possibly dispute the information released by CMS.
Organized neurosurgery strongly supports limitations on the release of raw payment data. At the very least, individual physician payment information should be presented together with relevant quality data to facilitate accurate and appropriate value-based decision making by consumers. Future policies should emphasize improvements in quality and efficiency, not cost reduction in isolation. If quality information is not available, cost and price information should, at the very least, be presented in as comprehensive a manner as possible (i.e., multiple payer sources), along with disclosures and/or explanatory statements as to the limitations and potential misinterpretations of such data and the importance of also considering quality in decisions about providers, treatments, and health care services.

As discussed earlier, we also urge Congress to enact policies that recognize the value and encourage the use of more robust clinical data collected from registries and other longitudinal databases. Federal quality improvement and value-based initiatives currently rely too heavily on claims data, which were developed for reimbursement purposes and are a crude metric for assessing the quality of medical care. Claims data are limited in their ability to capture more important clinical factors that affect patients, including case mix, co-morbidities, and other patient characteristics. Furthermore, Medicare claims data, in particular, constitutes only a portion of patients treated and services performed by many physicians.

Additionally, the development and testing of statistical methodologies to ensure the validity and reliability of data is foundational to ensuring its value to both physicians and the public. Both clinical and claims data require sophisticated analyses to result in useful, meaningful, understandable, and actionable information. Without statistically valid sample sizes and standardized risk-adjustment and attribution methods, multiple and conflicting reports could be published for the same physician, which undermines the usefulness of this data and could lead to misleading and inaccurate information about health care quality. Attribution and risk adjustment methodologies, in particular, remain far from perfect and can only be perfected over time and with a significant investment of resources. Without statistically valid sample sizes and standardized risk-adjustment and attribution methods, multiple and conflicting reports could be published for the same physician, which undermines the usefulness of this data and could lead to misleading and inaccurate information about health care quality. Attribution and risk adjustment methodologies, in particular, remain far from perfect and can only be perfected over time and with a significant investment of resources. Attribution and risk adjustment methodologies, in particular, remain far from perfect and can only be perfected over time and with a significant investment of resources.

Section 10322 of the Affordable Care Act (ACA) requires the Secretary to make Medicare claims data available to qualified entities (QEs) for the evaluation of provider performance on measures of quality, efficiency, effectiveness, and resource use. The provisions authorized under this section represent a solid foundation on which Congress should continue to expand policy related to appropriate data transparency. For one, the ACA requires that any report published by a QE based on the released data must include an understandable description of the measures, risk adjustment methods, physician attribution methods, data specifications and limitations, and other applicable methods so that consumers, providers, health plans, researchers, and other stakeholders can accurately assess such reports. In addition, the reports must be made available to any provider identified in the report, with an opportunity to appeal and correct any errors. Finally, the reports may include information on a provider or supplier only in an aggregate form as the Secretary determines appropriate.

Section 10322 also addresses another critical issue related to data transparency, which is the increased risk of liability exposure. This concern is significant among physicians and often hampers efforts to collect critical data and to improve the quality of patient care. In fact, the 1999 Institute of Medicine report, To Err is Human, actually noted that this "wariness" is a significant issue that stymies voluntary reporting and the free exchange of information and recommended that Congress pass "legislation to
extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.\(^2\)

Section 10322 of the Affordable Care Act (ACA) explicitly states that data released to QEs and any analyses and reports derived from such data cannot be subject to discovery or admitted into evidence without the identified physician’s consent. While organized neurosurgery greatly appreciates this protection, it only applies to a limited set of Medicare data released to QEs. We urge Congress to expand this provision so that it applies more broadly and incentivizes physicians to actively participate in performance measurement, reporting to clinical data registries and other quality improvement efforts.

We would also like to highlight some relevant legislation recently introduced in the House that would expand upon these protections. These include:

- The **Standard of Care Protection Act** (H.R. 4750/S. 1769), which would help ensure that provisions of law regarding federal health care programs are not used, outside their intended purpose, to create new standards of care for medical liability lawsuits. This bill clarifies that lawsuits could not be based simply on whether medical providers followed the national guidelines or payment policies created in federal health care laws; and

- The **Saving Lives, Saving Costs Act** (H.R. 4106), which would provide liability protections for physicians who follow evidence-based guidelines.

Finally, it is critical that the public’s use of healthcare data be carefully tracked. This includes not only the frequency with which they are accessing data, but how they are interpreting it and applying it. A recent poll conducted by the Associated Press-NORC Center for Public Affairs Research found that 6 in 10 people say they trust doctor recommendations from friends or family, and nearly half value referrals from their regular physician. However, the poll found far fewer trust quality information from online patient reviews, health insurers, ratings web sites, the media, even the government.\(^3\)

### 4. What barriers stand in the way of stakeholders using existing data sources more effectively and what reforms should be made to overcome these barriers?

We believe the answer to this question has been addressed in our previous responses.

**Conclusion**

There is no doubt that increased data transparency would be incredibly useful to help providers better understand and improve the care they are delivering and to help patients make more informed choices about their providers and treatment options. However, the unfettered release of such data carries many significant risks and could result in inaccurate and misleading information that could impede the goal of higher quality and more efficient care.

The AANS and CNS appreciate your consideration of our comments and look forward to working with you to further refine a strategy that balances the public’s information needs with protections that ensure appropriate and meaningful applications of healthcare data. Please feel free to contact us should you want to further discuss any of the concerns addressed in this letter.


\(^3\) Available at: http://tinyurl.com/n2wv8ph.
Sincerely,

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The **Surgical Quality Alliance (SQA)** is a collaborative effort of surgical and anesthesia specialty societies united to define the principles of surgical quality measures, collaborate in the development of meaningful tools for quality improvement, and provide a forum for shared and coordinated effort among the specialties to monitor and respond to federal and private sector initiatives.

The SQA members listed below developed this document.

- American College of Surgeons
- American Academy of Ophthalmology
- American Academy of Orthopaedic Surgeons
- American Academy of Otolaryngology–Head and Neck Surgery
- American Association of Neurological Surgeons/Congress of Neurological Surgeons
- American College of Osteopathic Surgeons
- American Pediatric Surgical Association
- American Society of Anesthesiologists
- American Society of Breast Surgeons
- American Society of Cataract and Refractive Surgery
- American Society of Colon and Rectal Surgeons
- American Society for Metabolic & Bariatric Surgery
- American Society of Plastic Surgeons
- American Society of Transplant Surgeons
- American Urogynecologic Society
- American Urological Association
- Society for Vascular Surgery
- Society of American Gastrointestinal Endoscopic Surgeons
- Society of Gynecologic Oncology
- The American Congress of Obstetricians and Gynecologists
- The Society of Thoracic Surgeons
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EXECUTIVE SUMMARY

The SQA recognizes the importance of publicly available reports on surgical care. Public reports can facilitate health care quality improvements by influencing physician behavior and decision-making and by informing payers and consumers on how to best sponsor or purchase care. However, many of the guidance documents in the public domain focus on primary care and do not sufficiently reflect important aspects of guidance for patients who need or have experience with surgical procedures.

The spectrum of defining quality is centered on the core principle of good surgical care, which should be defined and assessed by patients and their surgeons. However, there is no single definition of “quality.” Quality is currently defined by payers using primarily performance indicators that are most often process measures. Some of these measures are not fully supported by evidence and others focus on specific aspects of care that are not applicable in many instances. Performance measures need to improve if they are to be used for quality improvement and public accountability. Misuse of measures could lead to misclassification of care. This document is intended to focus on public reporting of data that characterizes the processes and outcomes of individual surgeons. However, the scope of publicly reported measures can include health-care providers or a facility. The principles of this document broadly apply to group-based reporting as well.

In addition to a surgeon’s need for accurate information, other stakeholders including patients, purchasers, and health plans need accurate information about quality of care; however, the needs of each stakeholder might carry a slightly different focus. Patients seek safe, effective, accessible care in an environment where the patient’s voice is heard. Purchasers and health plans emphasize safety, effectiveness in outcomes, appropriate use of resources, and competition. Providers wish to avoid misclassification and seek meaningful actionable performance feedback from reliable and valid sources. The function of a given report is determined by the intended audience, but the data source for the reports is often the same. This concept is illustrated in Appendix D in the Agency for Healthcare Research and Quality (AHRQ) figure titled Private Feedback Reporting Audiences, Functions, and Information Flow Diagram.

This document provides guidance to organizations that will be creating public reports for surgical care by highlighting methods and techniques intended to:

1. Accurately represent surgical care defined by providers
2. Report information that is understandable and valuable for a variety of audiences, including but in no way limited to physicians, patients, payers, and purchasers

The document consists of the following sections:

Section I: Basic Operating Tenets of Provider Public Reporting defines basic tenets to be considered in determining data to be publicly reported and describes the sources of that data.

Section II: General Issues in Reporting addresses issues to be considered when defining specialty-specific reporting metrics.

Section III: Audience-Dependent Issues reviews important audience-related factors to be considered to ensure that the message reported is understandable and relevant to the needs of the reviewer.

The appendix contains definitions of critical elements in the establishment of a process of public reporting of surgeon performance and a summation of the report’s recommendations.
**INTRODUCTION**

Personal and professional commitment to optimal patient care is the core value of the medical profession. Physicians recognize that the clinical responsibility entrusted to them is based on accountability to every patient. The scope of that accountability includes appropriate and effective therapy, patient safety, cost effectiveness, and optimal clinical outcomes. While these commitments are implied in the social contract of clinical care, federal legislation now mandates that these components of care be measured and publicly reported. The intent of this federal mandate is to assist patients in choosing options for their health care and to encourage providers to identify opportunities to continuously define and demonstrate improvement in quality and outcomes. Many components of care have been reported by other public and private entities, but many reports in past and current circulation are not reliably consistent or accurate.

The availability of public reports on surgical care is an opportunity for the surgical patient to proactively seek out high-quality care. Reports on surgical care are intended to increase patient decision-making as it relates to the care they seek and to develop specific expectations for that care. Quality in surgical care is made more complicated because patients have historically relied on referrals from their primary care physicians who may not be fully aware of the quality aspects specific to surgery. This means patients must interpret information available to them in public reports as well through the referral process. It is critical that this information is accurate, relevant, and meaningful to the surgical patient while avoiding unintended consequences.

There are both challenges and risks associated with a public reporting mandate. This fact is especially so when it is applied to surgical care, which encompasses many specialties, each of which has unique characteristics based on patient need. As modern surgical care has continued to become more sophisticated and technologically complex, it has stimulated the emergence of many subspecialties dedicated to specific types of diseases or special patient populations making the task of quality comparisons between physicians more complex.

Some surgical specialties are focused on the performance of many common operations on a generally healthy population, while others may care for patients with infrequent and complex disease who are unstable or gravely ill. Moreover, no surgeon operates alone. Even the most straightforward procedure requires a team to address everything from anesthesia to the provision of sterile instruments and the maintenance of safe surroundings for the complete care of the patient. Surgical care is the quintessential example of coordinated teamwork executing a reliable process of care safely, effectively, and efficiently—this fact is the core of what a public report about surgical care should convey.

In response to the differences inherent in reporting on surgical care for public reporting of surgeon performance and recognizing the almost innumerable variations of modern surgical specialty care, the SQA has developed this guide for patients, payers, purchasers, and health policy managers to help identify the data that are relevant to assessment of provider function, equitable for all providers, and truly effective in assisting patient choice and stimulating health care improvement. The fundamental message of this document is that surgical specialists, in consultation with their patients, working through their specialty societies and with quality measurement experts, are the most qualified to define meaningful definitions of clinical excellence. The process by which such determination is calculated may well include data from other sources; however, the final arbiter of clinical relevance and the pathway to optimal patient clinical outcome rests with the experts that are delivering care in the field.
SECTION I. BASIC OPERATING TENETS OF PROVIDER PUBLIC REPORTING

This section provides guidelines to assure that information in public reports follows requirements that are critical to reliable and valid surgical reporting. These recommendations will help to establish trust so that providers and their patients can be confident that reports accurately reflect surgical care.

Recommendations discussed in this section:

1. All reports should make their methodology publicly available and should include a detailed description of any data used to estimate performance (i.e., the data source), use of statistical risk-adjustment techniques, the selection of performance measures, and how surgical performance was categorized. Reporting bodies should not use “black box” proprietary measures, which make it impossible to audit the report results.

2. Each report should be independently deemed reliable and valid prior to release.

3. Reports must be transparent about the observation period for a given quality measure, including the differentiation between long-term follow-up and short-term outcomes.

4. Include a statute of limitations within the public report. Outdated reports must be removed from circulation.

5. Use proper risk adjustment, as determined by the appropriate specialty society, to ensure ongoing access for patients who are at higher risk of complications and poor outcomes.

6. Ensure that specialty societies have an opportunity to provide input regarding recommended physician measures chosen for public reporting and participate on the workgroup or panel selecting measures for the reports.

7. Standardize reporting format.

8. Provide opportunity for individual surgeon review and feedback before public reporting. Ensure a proper appeals process, including the process for managing contested reports.

9. Conduct pilot tests to determine usefulness and effectiveness of reports.

10. Evaluate the extent to which the report fulfills its stated purpose and identify any unintended consequences with special focus on addressing misclassification.

11. Public reports should not be used to establish the standard of care or duty of care owed by a health care provider.
1. All reports should make their methodology publicly available and should include a detailed description of any data used to estimate performance (i.e., the data source), use of statistical risk-adjustment techniques, the selection of performance measures, and how surgical performance was categorized. Reporting bodies should not use “black box” proprietary measures, which make it impossible to audit the report results.

Misclassification of the quality performance of surgeons in public reports must be avoided through the use of rigorous statistical analysis. For the purposes of this document, performance misclassification in public reporting refers to reporting a provider’s performance in a way that does not reflect the provider’s true performance. It is also important to include measures with publicly available specifications to ensure the use of a common set of clinically relevant measures that have been properly evaluated for fairness and accuracy and that can be aggregated and compared across broad populations for meaningful analysis. To this end, providers and those reviewing the report should have access to the measure specifications to understand how they are being measured. Furthermore, “black box” quality metrics must be avoided for these reasons. Theoretically and for reasons of transparency, it should be possible for others to replicate the developer’s methodology so that the reported metrics can be supported by statistical analysis.

2. Each report should be independently deemed reliable and valid prior to release.

Parameters on volume should be included to ensure that the publicly reported data is statistically significant. For example, a recent analysis demonstrated that out of 14 commonly-used facility-level primary care measures, only 4 of those measures were able to achieve reliability (reliability of at least 0.70) with 31 observations or less.1,2 Two of these measures required more than 200 observations to achieve reliability.1,2 To this end, the number of observations that would allow for valid comparisons should be made on a measure-by-measure basis.

With the need for risk-adjusted data, minimum volume levels must be required to help ensure that the data is truly representative of the surgeon and/or surgical group. In turn, no maximum volume criteria should be required. Surgeons may not do enough of some specific procedures to be assessed or compared on performance. For instance, low volumes could be due to the size of the community the surgeon serves or due to the rarity of the procedure. Therefore, reports on surgeons having too few procedures to accurately characterize performance should A) not be included in public reporting and B) clearly state that information could not be reported due to sample size. Report developers should also include a statement that inadequate numbers of procedures or patients—that do not allow for acceptable reliability—in no way reflects upon the performance of the surgeon.

3. Reports must be transparent about the observation period for a given quality measure, including the differentiation between long-term follow-up and short-term outcomes.

Reports must be transparent about the information being reported by a given quality measure, including an explanation of the measure’s observation period. This will provide the patient with a more accurate snapshot of the care being measured and help to better meet patient expectations. Focus on short-term outcomes may be inappropriate for some procedures and could create a perverse incentive in certain cases. For example, 30-day outcomes of lower extremity revascularization procedures would likely favor prosthetic bypass or endovascular procedures compared with autogenous reconstruction; however the long-term results would overwhelmingly favor autogenous bypass. Another example is 30-day cosmetic outcome after partial mastectomy for breast cancer or 30-day outcome after mastectomy with immediate reconstruction. The early assessment of cosmetic outcome may differ substantially from results in both cases.3 Furthermore, 30 days is likely an inadequate length of time to measure performance for cancer outcomes due to few events, highlighting a need for longitudinal assessment.3
4. Include a statute of limitations within the public report. Outdated reports must be removed from circulation.

The statute of limitations that applies to any report should be clearly visible at the front of the report. A detailed list for the statute of limitations can be found in Appendix A. To ensure correct interpretation by all potential users, public reports should reflect the most accurate and current information. To enhance user understanding of public reports, developers are advised to include the report’s assessment period within its name, for example, Surgical Assessment Calendar Year 2012 or Surgical Performance March 2011 – March 2012.

5. Use proper risk adjustment to ensure ongoing access for patients who are at higher risk of complications and poor outcomes, as determined by the appropriate specialty society.

There can be vast differences in the course of disease or response to care between groups of patients with the same diagnoses. For example, diabetes can be mild, controlled, brittle, or uncontrolled. The variations are difficult to measure and have significant implications on surgical decision-making. Other conditions that increase the complexity of surgery are difficult to accurately convey in public reporting mechanisms. For example, a history of previous fracture in a patient undergoing knee replacement can make surgery markedly more complicated, yet it is difficult to accurately convey this in public reports. Further, there is growing evidence that patients’ socioeconomic status can be a predictor of poor patient surgical outcomes in some procedures.4,5,6

It is critical for report developers to use only the most rigorous risk-adjustment methodologies available when reporting quality measures, as determined by the appropriate surgical society. The appropriate risk-adjustment methodology will protect surgeons from unfair comparisons, regardless of their patient case mix. An example of this is the National Consortium of Breast Centers (NCBC) measure “timeliness of care in patients undergoing surgery for cancer” (measured from the date of diagnosis to date of surgery).7,8,9 As part of this program, the NCBC provides confidential peer performance comparison, driving quality improvement. If the NCBC timeliness metrics were publicly reported, they would need to be risk-adjusted for whether the patient underwent preoperative magnetic resonance imaging (MRI), genetic testing, systematic imaging, plastic surgical consultation, and neoadjuvant chemotherapy, because they all affect timeliness.8 If these factors were not included in the risk adjustment, then the comparison between patients would be unfair.

To better ensure ongoing access to patients who are at higher risk of complications and poor outcomes, surgeons and anesthesiologists should reinforce the need for balance in implementing public reporting systems with the increasingly urgent need to improve quality. Critical to this balance is the importance of developing clinically valid and appropriately risk-adjusted performance measures which have been analyzed for relevance and validity. To this end, surgeons should support ongoing research into measure development and proper risk adjustment of all publicly reported outcome measures as performed by established programs such as The Society of Thoracic Surgeons National Database, the American College of Surgeons National Quality Improvement Program (ACS NSQIP®), the National Neurosurgery Quality and Outcomes Database (N2QOD), and the National Anesthesia Clinical Outcome Registry (NACOR).

It is important to note that entities reporting on quality should take care when adjusting for American Society of Anesthesiologists Physical Status classification (ASA PS) score, which is a classification system designed to help define risk of anesthesia and, in that regard, reflect overall patient physiologic status. The ASA PS score is frequently cited in relation to disease severity. Although a lack of interrater reliability has been demonstrated when assigning the ASA PS score, it has proven to be valid and may be useful as a risk adjustment variable.10,11,12
6. Ensure that specialty societies have an opportunity to provide input regarding recommended physician measures chosen for public reporting and participate on the workgroup or panel selecting measures for the reports.

Surgeons (content experts) have a great familiarity with their field, clinical management, and the published research. Having measures vetted by a surgical technical review committee will better ensure that the measure specifications accurately reflect surgical care. Involving surgeons, including subspecialty surgical stakeholders, on workgroups creating the report will also create a culture of collaboration among stakeholders. It is recommended that members of the workgroup have familiarity with performance measures and/or consult and collaborate with quality measurement experts. As a result, each subspecialty can decide and rank the importance of which quality measures best reflect their care.

7. Standardize reporting format.

Report format and content should be standardized in order to provide clear and comprehensible presentation of data and the analytic mechanisms used to derive that data. Without a standardized format, consumers will not be able to make “apples-to-apples” comparisons or well-informed decisions about their care. It is critical that the various reporting entities use the same definitions to make meaningful comparisons of patients with the same occurrences.

8. Provide opportunity for individual surgeon review and feedback before public reporting. Ensure a proper appeals process, including the process for managing contested reports.

Allow physicians at least 90 days to review the reports prior to making the reports publicly available, at least 30 business days to request data used in the report, and 30 days to request error correction to review reports before they are made public in order to identify errors with confirmation that those errors have been acknowledged by the reporting entity and will be addressed. The reporting entity should not be permitted to publish unresolved contested reports without the consent of the provider or supplier.

Specifically, report developers should outline to the surgeon the purpose and details of the report, the actions the surgeon should take to verify its contents, the method(s) to submit feedback, the expected date of public dissemination of the report, and a deadline for feedback. Also, information should be provided on how and when the surgeon will receive a response to their feedback. The report developer should provide methods of contact (for example, via mail, telephone, e-mail, and so on) to assist the surgeon with any questions. Surgeons who receive reports to review need to have access to a regionally based network of clinical managers who are available to discuss the details of the report with the surgeon and provide a more detailed report. The surgeon should also be able to engage with the Medical Director of the reporting organization or institution, if needed.

In addition to reviewing information contained within the report, an explanation of the report methodology should also be provided. This information should mirror the items previously outlined in the first recommendation. The individual physician’s data used to populate his or her report should be made available if requested.

Additionally, a true appeals process is critical to avoid misclassification. The lack of a true appeals process is unfair, especially given the potentially adverse consequences of an inaccurate report to a surgeon’s reputation and practice. Therefore, physician information should not be made public until the appeals process is complete, including consent of the provider. If the request for a data or error correction is still outstanding at the time of making the reports public, the reporting body should publicly post the name of the appealing provider and a description of the appeal request.
9. **Conduct pilot tests to determine usefulness and effectiveness of reports.**

The report developer should produce confidential reports for the intended audience of the report to pilot test proposed measures and methodologies used to analyze and report data. The pilot will also allow for report developers to test the effectiveness of the report on the intended audience. This process will allow for report makers to provide confidential feedback to providers and allow for proper scrutiny and discussion so that providers can understand the attribution and risk adjustment methods. This course of action will build provider trust.

10. **Evaluate the extent to which the report fulfills its stated purpose and identify any unintended consequences with special focus on addressing misclassification.**

Data included within the report should be timely and reflective of current performance and standards of care, including technological advances. Older data may reflect performance that is dated through changes in technique or technology and be less relevant to current practice. Measures can become irrelevant after new evidence is published. An example is the quality measure “Proportion of patients with a positive SLNB (as defined by micrometastases greater than 0.2 mm) who received a cALND,” which became irrelevant after two years with the publication of a randomized clinical trial. Another example is the change in the type of bariatric procedures being performed with an increase in the use of lap bands. This change has created a shift in technology, which also changes the underlying quality and comparison data. Public reports should be reflective of changes to ensure that the most current procedures available are reported to the patient. To this end, public reports should define their expiration date when published and be removed from circulation once expired (for example, removed from the report developer’s website).

11. **Public reports should not be used to establish the standard of care or duty of care owed by a health care provider.**

While the availability of public reports on surgical care is an opportunity for the surgical patient to proactively seek out high-quality care, and these reports are intended to increase patient decision-making as it relates to the care they seek and to develop specific expectations for that care, public reports should nevertheless not be used to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice action or claim. The medical liability system is already overburdened by meritless litigation, and it is important that such public reports are not misused to create new standards of care for medical liability lawsuits.
SECTION II. GENERAL ISSUES IN REPORTING

This section addresses issues to be considered when defining surgical specialty-specific reporting in order to better ensure accurate metrics.

Recommendations and issues discussed in this section:

1. Clinical data generally provide more accurate and relevant information compared with claims data and should be used solely or in combination with claims data. Local, state, and federal government agencies as well as regional and national specialty societies that have supported registries that produced high-quality clinical data audited for completeness and accuracy and provided a basis for risk adjustment models that appropriately account for patient severity are well-suited to generate public reports.

2. Attribution must distinguish between the primary surgeon and other practitioners managing the various components of the surgical procedures and perioperative care.

3. Appropriateness criteria must be driven by evidence-based medicine or clinical guidelines with multi-stakeholder consensus, similar to the rigorous standards for quality measurement.

4. Public reports must accurately describe surgeons’ practice profiles.

5. Data in reports must be defined by and relevant to procedures being reported.

What type of data should be utilized in public reporting?

1. Clinical data generally provide more accurate and relevant information compared with claims data and should be used solely or in combination with claims data. Local, state, and federal government agencies as well as regional and national specialty societies that have supported registries that produced high-quality clinical data audited for completeness and accuracy and provided a basis for risk adjustment models that appropriately account for patient severity are well-suited to generate public reports.

Administrative data are routinely collected and are relatively inexpensive to analyze, and they often, but not always allow for easy identification of geographical and ethnic subgroups with particular access problems. However, administrative data do not address the nuances of comorbidities, severity, conditions present on admission, complications, and patient experience, and do not enable adequate risk adjustment. For example, body mass index (BMI) is not captured in claims data and is an essential variable when assessing the quality of bariatric surgery. The Centers for Medicare & Medicaid Services (CMS) has recognized the limitations of claims-based data, acknowledging that it has been created for billing purposes and not for quality reporting.

Clinical data are more accurate and comprehensive, but they are expensive and often difficult to obtain due to variations in how hospitals and physicians collect and document data. Although there is a clear preference for clinical data, due to the cost of obtaining various types of clinical data, the enhancement of administrative data in combination with clinical data sets may be both practical and advantageous. A recent pilot project with AHRQ and the Minnesota Hospital Association found that the use of hybrid data sets allowed for more accurate comparisons of risk-adjusted mortality and risk-adjusted complications across Minnesota hospitals. In the future,
electronic health records (EHRs) must be able to provide appropriate, structured, and validated data that will drive processes designed to substantially improve the cost, quality, and access to relevant, timely clinical information.

Benefits of using clinical data for public reporting:
- Clinical data more directly reflect the delivery of care.
- Unlike administrative data, which aggregates experience for system management requirements, clinical data are patient specific and can be more precisely stratified to define best practice.

Limitations of claims-based data for public reporting:
- Hospital coding compiles specific diagnosis codes into diagnosis-related groups that define reimbursement rather than reflect an accurate sequence of clinical events that define clinical care delivery.
- Attribution of causality or association with adverse events to specific providers is not possible with aggregated data.
- Inconsistency in definitions of terms and coding makes the data less reliable for quality reporting. The coder must often interpret what the physician has documented, which adds the unaccountable subjective bias of both.
- There are no standardized methods for attribution of providers’ roles in patients’ episodes of care.

Examples of registries that meet or exceed the outlined criteria include state registries such as the New York Cardiac Surgery Reporting System (CSRS), the New Jersey Cardiac Report Card, and the Pennsylvania Health Care Containment Council. The United States Department of Veterans Affairs’ Continuous Improvement in Cardiac Surgery Program is an example of a government agency well-qualified to report. The Northern New England Cardiovascular Disease Study Group is an example of a regional collaborative to drive quality improvement in cardiac surgery. The Society of Thoracic Surgeons National Database and the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP®), and the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) are examples of a well-established and highly representative national databases actively supported by a specialty society.19

It is important to recognize that no registry is perfect. Registries designed to provide confidential data feedback and support collaborative quality improvement must be tested for validity, feasibility, and reliability when the data is being used for accountability. It cannot be assumed that programs, which ensure confidential reporting, will function identically in an accountability environment. If payment differentials are at stake it is likely that there will be strong pressure to either make patient risk seem as high as possible and/or limit any report of an adverse outcome.
What are acceptable methods of attribution?

2. Attribution must distinguish between the primary surgeon and other practitioners managing the various components of the surgical procedures and perioperative care.

The method of attributing responsibility for various components of patient care to specific surgeons can greatly impact the outcome and accuracy of physician performance reports. There are two general categories of attribution:

- Single physician attribution, where patient care is attributed to a single physician who is presumed to have overall management responsibility for the patient’s management.
- Multiple physician attribution, where a patient’s care is attributed to all or a majority of the physicians who played a role in the care of the patient, including when a specialist is managing the patient but another surgeon is performing the surgery. An example includes cancer outcomes measured by overall survival (OR), disease-free survival (DFS), and locoregional recurrence (LRR), where the combined use ensures that cancer outcomes are not solely attributed to one type of surgeon (colorectal, pancreatic, breast, and so on) but are instead dependent upon the collective performance of the surgeon, medical oncologist, radiation oncologist, imagers, and so on.

With the progressive evolution of shift-related surgical coverage stimulated by the modern environment of work hour restrictions for residents, single physician attribution will become increasingly less relevant and reliable. Further, the complexity of many clinical treatments today requires a team of clinicians with complementary skills in order to achieve optimal patient outcomes.

There are several additional surgery-specific issues related to multiple and single attribution. First, it is not always possible to accurately attribute care to multiple physicians when utilizing claims data alone. Attribution methodologies may rely on identifying the physician who provided a plurality of the patient’s care as defined by the number of specific services or charges. There is a possibility that surgeons who provide a single discrete service may not have their patients properly attributed to them under this method. Or, the surgeon may be attributed to elements of a patient’s care that the surgeon may have little control over included as part of their attribution, such as imaging and other tests. This makes it necessary to carefully apply appropriate severity scoring or multiple attribution.

What are acceptable methods for measuring appropriateness?

3. Appropriateness criteria must be driven by evidence-based medicine or clinical guidelines with multi-stakeholder consensus, similar to the rigorous standards for quality measurement.

Appropriateness is an important factor of high-quality surgical care. Appropriateness criteria should follow similar rigorous standards applied to quality measures, including multi-stakeholder expert consensus, evidence-based medicine, and the use of clinical guidelines, where applicable. It is critical that unintended consequences are closely monitored so that there is not a reduction in the volume of delivery of appropriate care as a result of appropriateness criteria. Guidance can be found in the process used by CMS in the recently completed the Medicare Imaging Demonstration project, a two-year initiative that collected data on the appropriateness of services in relation to established criteria and physician peers. Guidance from specialty societies on appropriate care is also available from the Choosing Wisely Campaign, an initiative of the American Board of Internal Medicine. As part of this initiative, specialty societies have identified five tests or procedures that are sometimes not necessary and therefore warrant a conversation between the physician and patient. The goal of the initiative is to help make the most appropriate decisions on the necessity of care based on individual patient needs. For more information on Choosing Wisely, visit www.choosingwisely.org.
Additional surgery-specific issues:

4. **Public reports must accurately describe surgeons’ practice profiles.**

In addition to determining what is publicly reported, surgical specialties must decide what should or should not be included in the surgeon profile. Public reporting should focus on common procedures of a specialty. Relevant information such as participation in Maintenance of Certification (MOC) and completion of Continuing Medical Education (CME) should be included. Certain information such as license information, educational background, and pending lawsuits or disciplinary actions should not be included in a profile. Updating and maintaining a large amount of basic information will be a burden for staff and therefore should be limited. The surgical specialty can draw minimal and basic information from the surgeon/surgeon group; this step is recommended to identify the surgeon group and will require the least amount of updating.

5. **Data in reports must be defined by and relevant to procedures being reported.**

When patients view public reports, it can be challenging to determine the type of care a physician provided to determine their score on quality or cost measures. Defining data by procedure (i.e., by CPT code) is the clearest way to define the care that patients received. Many reporting formats currently utilize episode groupers to analyze all of the costs associated with a particular “episode” of care. While the concept might hold promise, determining validity for episode groupers requires further analysis and testing.

Even if episodes are used, it is important for the physician to have access to a clear and concise description of the specific procedures included in the episode so that he or she can evaluate the accuracy of the data. Similarly, patients should be able to understand the services that are being presented so that they can evaluate the information reported on their physician. Specific recommendations on how to tailor the report to patients can be found in the Audience-Dependent Issues section of this report.
This section provides recommendations regarding which information on surgical quality is relevant to specific audiences—physicians, patients, and payers/purchasers—and how to report the data source in a way that is meaningful to each intended audience. The function of a given report is determined by the intended audience, but the data source for the reports is often the same. This concept is illustrated in Appendix D in the AHRQ figure titled Private Feedback Reporting Audiences, Functions, and Information Flow Diagram.

It is important to keep in mind that there is a continuous evolution of quality measures which define the current public reporting and quality improvement environment. These recommendations address public reporting resources and methodologies in the current (2014) health care system. However, because the health care system is rapidly evolving, these recommendations will need to be adapted to upcoming payment structures such as Accountable Care Organizations (ACOs) and episodes of care.21

PHYSICIAN AUDIENCE

Recommendations discussed in this section:

1. Consider principles crucial for physician engagement.
2. Tailor a confidential performance feedback report specifically for the surgeon.
3. Report on the type of quality measures meaningful to physicians, including Donabedian’s system approach (structure, process, and outcome) and AHRQ National Quality Measures Clearinghouse domains for clinical quality measures (process, access, outcomes, structure, patient experience), appropriateness of care/resource use, shared decision-making, care coordination, and continuity of care.
4. When choosing measures for physician public reporting or payment, consult evaluation criteria used by the leading major national organizations.

Public reporting provides the opportunity for surgeons to self-assess the quality of their care in comparison with their peers and to track opportunities for containing cost to provide more affordable care. A recent AHRQ review suggests that health care providers’ more often engage in activities to improve quality when reports are made public, and public reporting is associated with improvement in performance measures.22

Public reporting for physicians must be:

- Relevant
- Timely
- Complete
- Accurate

Continued integration of EHRs could help make the challenge of meeting these goals easier. In theory, this would provide access to real-time quality measurement allowing physicians to go beyond measuring an outcome to preventing adverse outcomes and efficiencies. However, there are many obstacles the U.S. health care system must overcome to achieve full integration of EHRs. Below are the steps outlined to improve physician performance feedback reports for self-assessment and facilitation of improvements in care as well as physician engagement in public reports.
1. Consider principles crucial for physician engagement.

The principles outlined include recommendations for report developers to consider when creating public reports on surgeons for review by patients, payers and purchases, and other audiences. These principles are recommended with the intent to increase report accuracy, and physician trust and collaboration.

(Adapted from the Wisconsin Collaborative for Healthcare Quality, American Medical Association Guidelines, and the SQA)

   a. Surgeons need timely reports, not annual reports from prior years.
   b. Surgical specialties should define the criteria to include or exclude measures.
   c. Encourage the use of performance data that are valid, reliable, and trusted by physicians and that are attentive to the details of sample size, bias, risk adjustment, and attribution. There must be a clear definition of risk adjustment and/or stratification used and how this allows for peer comparisons.
   d. Provide access to measure specifications, peer-performance, and health plan targets.
   e. Ensure adequate depth of data available to physicians, including patient-specific data for validation purposes.
   f. Require surgeon-led development of performance measures. It is crucial that surgeons determine the minimal quality threshold, benchmark, and target goals for each measure of quality after reviewing the best evidence available.
   g. Emphasize a focus on quality of patient care as the goal of reporting.
   h. Require sharing of best practices across a consortium of quality improvement-driven health care organizations.
   i. Encourage reporting at the level of the organization acknowledges that health care delivery is an outcome of the actions of many individuals and the systems that support them.

2. Tailor a confidential performance feedback report specifically for the surgeon.

Private reports provide physicians with granular information needed to take specific action to improve quality. Confidential performance feedback reports may be provided by health plans or group practices for internal quality improvement. They may also be provided as a parallel report to public reports with detailed information relevant to individual quality improvement. For guidance on the design, dissemination, and use of private physician reports, reference AHRQ’s report “Private ‘Performance Feedback’ Reporting for Physicians: Guidance for Community Quality Collaboratives,” which is available at www.ahrq.gov/professionals/clinicians-providers/resources/privfeedbackgdrpt/index.html.

3. Report on the type of quality measures meaningful to physicians, including Donabedian’s system approach (structure, process, and outcome), AHRQ National Quality Measures Clearinghouse domains for clinical quality measures (structure, process, outcomes, access, patient experience), appropriateness of care/resource use, shared decision-making, care coordination, and continuity of care.

SQA supports the Donabedian taxonomy of structure, process, and outcome and the AHRQ National Quality Measures Clearinghouse domains for clinical quality measures (QM) (process, access, outcomes, structure,
patient experience) for quality improvement. Surgeons appreciate key process measures linked closely to outcomes, outcomes measures, appropriateness, shared decision making, care coordination, and continuity of care. Leadership from surgical specialty societies is important in the process of ranking and choosing the most important quality measures in each domain. The process of ranking and choosing measures should be done on a two- to five-year cycle so that quality measures reflect the most recent evidence in patient care.

- **Structural.** Structure refers to the physical and organizational properties of the settings in which care is provided. Many entities have included structural measures because of the ease of collecting that type of information. However, while collection burden can be low, structural measures do not always provide the best data. For example, procedural case volume by program is the most commonly used structural quality measure, but its use must be determined on a procedure-by-procedure basis.\(^{28}\) Furthermore, research findings have suggested that surgeons are not always confident that there is a relationship between the number of cases and the quality of care a patient receives.\(^{29}\) A recent study by LaPar et al found that hospital procedural volume is a poor predictor of mortality for pancreatic resection (PR), abdominal aortic aneurysm (AAA) repair, esophageal resection (ER), and coronary artery bypass grafting (CABG). Therefore, procedural volume should not be used as a proxy measure for surgical quality.\(^{30}\)

- **Process of Care.** Process measures are information-based processes that are used to educate surgeons on the steps they follow when delivering care. Inclusion and exclusion criteria must be carefully specified. When process measures are used for physician public reporting, they should have a causal link to outcomes and should be proximate to those outcomes.\(^{28}\)

- **Outcome Measures.** Outcome measures refer to the results of the intervention in terms of patient health status. Outcome measures are regarded as the most important quality metrics. They are supported by evidence that the measure has been used to determine the results of one or more clinical interventions. It is important that outcome measures include provisions for risk adjustment.

- **Access.** Access measures the ability to attain timely and appropriate care. Access measures demonstrate that an association exists between access to care and the outcomes of or satisfaction with that care.\(^{31}\)

- **Patient Experience.** Patient experience is a measure of performance of care received from the patient’s or caregiver’s perspective through use of a patient survey or other methodology.

- **Appropriateness of Care.** Appropriateness of care measures are determined by a valid, peer-review process to address both overuse and underuse.\(^{28}\) Appropriateness of care balances risk and benefit of a treatment, test, or procedure in the context of available resources for an individual patient with specific characteristics.\(^{32}\)

- **Shared Decision-Making.** Shared decision-making measures determine the communication between providers and patients in making health care decisions that are informed by the best evidence, potential benefits, and harms, and that consider patient preferences.\(^{33}\) Recently, surgical specialty organizations have developed patient risk calculators in order to drive shared decision-making. Examples include the American College of Surgeons Patient-Specific Surgical Risk Calculator and risk calculators from The Society of Thoracic Surgery and the American Society of Breast Surgeons.

- **Care Coordination and Care Continuity.** Care coordination measures determine whether patient needs and preferences for care are understood and that accountable structures and processes are in place for an effective comprehensive plan of care across providers and settings.\(^{34}\)
Types of measures that need to be carefully considered prior to use in public reports:

- **Morbidity and Mortality Outcomes.** Many databases do not collect out-of-hospital events, which results in an underreporting of morbidity and mortality in the 30-day interval post-discharge.\textsuperscript{29,35} Additionally, risk-adjustment methodologies are a subject of much debate when reporting on morbidity and mortality.

- **Composite.** To provide a more complete picture of quality, organizations such as the Institute of Medicine (IOM) recommend use of multidimensional composite measures. However, it is important for public reports to include a breakdown of the individual assessment of the measures contained in the composite, particularly when attempting to provide feedback on individual physicians for quality improvement purposes.\textsuperscript{36}

5. When choosing measures for physician public reporting or payment, consult evaluation criteria used by the leading major national organizations.\textsuperscript{37,39}

These criteria include the importance of the measure, reliability and validity, usability, and feasibility. Also critical is consensus among stakeholders, especially among surgical societies.

**PATIENT AUDIENCE**

Recommendations discussed in this section:

1. Report on patient-focused measures that are more likely to be understood by and credible with patients.

2. Public reports for patients should focus on elective surgical procedures because the majority of patients in emergent care situations will not have the opportunity to review public reports on surgeons.

3. Tailor a report specifically for the surgical patient.

4. Customize reports based on procedures, conditions, and populations of interest to the patient.

5. Reports should provide a framework to foster patient understanding.

6. Make information available at the time when patients are most likely to use it.

7. Establish credibility of reports from the patient perspective.

To date, patient-directed reports have been difficult for patients to understand, and they appear to have little impact on patient choice.\textsuperscript{22} When choosing their health care provider, patients rarely have access to public reports on clinical quality measures and therefore often review reports that include individual physician characteristics. However, individual physician characteristics such as type of medical degree, years of practice, malpractice claims, medical school ranking, and disciplinary action are unreliable proxies for performance.\textsuperscript{39} Health Grades is an example of reporting based on unreliable proxies of performance. Rather than utilizing these proxy measures, public reporting of quality information will provide patients with more meaningful information for choosing high-quality care. Many issues must be considered when creating, explaining, and disseminating clinical quality reports to surgical patients.
SECTION III. AUDIENCE-DEPENDENT ISSUES

1. Report on patient-focused measures that are more likely to be understood by and credible with patients.21

Consumers often have difficulty understanding technical aspects of quality reporting; therefore, when presenting clinical quality information cognitive burden must be considered. A critical priority is increased consumer education on provider variation in quality. It is important to choose measures that patients can understand and are meaningful. Measures must be valid, short, concise, and understandable. All measures that are to be used in patient reports should be tested for effectiveness among relevant patient populations.

- **Outcome measures on elective procedures**
  - Consider mortality carefully. In general, mortality statistics are not always useful because they may not be captured accurately by many databases.29 Additionally, surgical patients are interested in not only their 30-day survival rates but also but long-term outcomes.28

- **Composite measures by condition or elective procedure**
  - Consider a composite roll-up measure to simplify the report for patients. In this case there must be careful consideration on how much weight each individual measure should have within a composite.37 Composite measures are increasingly important for procedures with low mortality rates.

- **Measures tailored to demographics or health status**

- **Functional status measures**

- **Patient-reported measures, including validated patient-experience surveys**

- **Appropriateness of care measures as determined by a valid, peer-review process to address both overuse and underuse**28

**Additional information necessary to report:**

2. Public reports should focus on elective surgical procedures because the majority of patients in emergent care situations will not have the opportunity to review public reports on surgeons.

It is an unnecessary use of health care resources to publish reports on emergency procedures for review by patients because there will likely not be an opportunity for patients to review reports prior to receipt of care.

3. Tailor a report specifically for the surgical patient.

The report must define quality from the surgical perspective and educate consumers on the variation in surgical provider quality. In order to best format the report for patients, there are several resources available that can be adopted for the surgical patient.

- For examples of how report elements can provide separate information for consumers versus providers, review AHRQ’s report “Model Public Report Elements: A Sampler” at www.ahrq.gov/legacy/qual/value/pubrptsamp1b.htm.
4. Customize reports based on procedures, conditions, and populations of interest to the patient. Allow for an online function for individualized reports so that patients can review information they value. Promote the creation of one multi-payer report for a geographic area to promote visibility and credibility for better patient understanding.


5. Reports should provide a framework to foster patient understanding.

Consider the Institute of Medicine’s (IOM) six aims, which outline that care should be: (1) safe; (2) effective; (3) timely; (4) patient-centered; (5) efficient; and (6) equitable. Case-mix adjustment methodologies determined by professional surgical societies, which are meaningful and practical, will better ensure accurate and understandable information for the surgical patient.

6. Make information available at the time when patients are most likely to use it.

A Web-based platform has been promoted by stakeholders, but this may require multiple versions based on the intended audiences.

7. Establish credibility of reports from the patient perspective:

- Promote the creation of one multi-payer report for geographic area to promote visibility and credibility for better patient understanding.
- Legitimize the report sponsor’s credibility as an organization well-suited to report.
- List potential sources of misclassification and explain which ones have been addressed and by which method. Misclassification refers to reporting a provider’s performance in a way that does not reflect the provider’s true performance. The Five Point Checklist by Friedberg and Damberg published in Health Affairs has been developed as a tool to prevent misclassification.
- Engage patients in focus groups, surveys, or other methods for ascertaining patient perspectives to test reports for credibility.

PAYER/PURCHASER AUDIENCE

Recommendations discussed in this section:

1. Consider the Consumer-Purchaser Disclosure Project’s 10 criteria for meaningful and usable measures of performance.

2. Surgeons and surgical specialties need to continue to develop more robust data sources to supplement/aggregate with administrative and enrollment data to partner with health insurance plans in quality improvement. Should include clinical data as well as patient experience data.

3. Health insurance plans and purchasers need to continue to consider regional data aggregation partnerships and how to expand from preventive care and chronic disease management into surgical performance measurement. Plans and purchasers could also provide increased resources for specialty groups to develop and implement quality measures and patient experience of care surveys.
Health insurance plans and large employers, both public and private, have common goals in increasing the quality and efficiency of the health care system. Outside of accreditation for facilities and care delivery organizations, measurement by or for payers and purchasers has provided the data for the majority of population- or community-level quality improvement initiatives for decades.

The National Committee for Quality Assurance’s Healthcare Effectiveness Data and Information Set (HEDIS®) continues to be the primary basis of the measurement and public reporting for health insurance plans but concentrates almost exclusively on preventive care and the management of chronic conditions such as diabetes and hypertension with no evaluation of surgical care. Historically, health insurance plans have been limited to administrative claims and beneficiary enrollment information as data sources for both physician- and hospital-level performance measurement. Examples of measures used in pay-for-performance incentive programs have included Surgical Care Improvement Program (SCIP) measures such as antibiotic and deep vein thrombosis prophylaxis, adverse postoperative event rates, risk-adjusted outpatient surgeries Per Thousand Members Per Year (PTMPY), coronary artery bypass graft and hip and knee replacement, and hospital-acquired infections.42

HEDIS hybrid data collection methods (identifying the numerator through both administrative data and medical record data), the proliferation of electronic medical records, and aggregation and/or use of other data sources such as the Leapfrog Hospital Rewards Program, ACS NSQIP, the American College of Cardiology National Cardiovascular Data Registry, and The Society of Thoracic Surgeons National Database have increased the amount and accessibility of clinical data for health insurance plans. A health insurance plan has even partnered with Zagat for supplemental patient experience and satisfaction data through a Web portal survey.43 Most recently in 2012, United Healthcare has expanded its physician incentive programs to incorporate data from the American Gastroenterological Association’s Digestive Health Outcomes Registry.

Health insurance plan efficiency research literature is quite limited. Measurement of resource use and efficiency has previously been accomplished through vendor-based proprietary methods, which are episode-based or population-based. Other resource use measures used are often reported as a ratio adjusted for patient risk such as observed-to-expected ratios of costs per episode of care.44 “Proxy” efficiency measures such as inappropriate process or overuse measures are not adequate replacements for efficiency measures that address readmission rates and overall cost of care for health insurance plans.

In addition to incentives for providers such as referral and payment incentives, health insurance plans may use performance measures and communications with beneficiaries to aid in the selection of providers (in other words, preferred providers, tiering co-payments). Active participation in national performance measurement activities increasingly offers value-based information for large employers and other purchasers in health plan selection.

The actual use of HEDIS reporting and health insurance plan rankings has been reported as limited, which, based on similar literature on consumers, might indicate purchasers are not as interested in clinical performance measures or patient satisfaction as they might be in prompt payment of claims, lower prices, and large networks of physicians before they offer open enrollment to their employees.45 Nevertheless, large employers and purchasers have been actively engaged in health policy and have encouraged public reporting of health care data for consumers and purchasers through the National Business Group on Health and various regional organizations, the National Partnership for Women and Families, and the Consumer-Purchaser Disclosure Project.
1. Consider the Consumer-Purchaser Disclosure Project’s 10 criteria for meaningful and usable measures of performance.

The Consumer-Purchaser Disclosure Project, an informal coalition of stakeholders in consumer advocacy organizations and large purchasers, has emphasized 10 criteria for meaningful and usable measures of performance.46

1. Make consumer and purchaser needs a priority in performance measurement.
2. Use direct feedback from patients and their families to measure performance.
3. Build a comprehensive “dashboard” of measures that provides a complete picture of the care patients receive.
4. Focus measurement on areas of care where the potential to improve health outcomes and increase the effectiveness and efficiency of care is greatest.
5. Ensure that measures generate the most valuable information possible.
6. Require that all patients fitting appropriate clinical criteria be included in the measure population.
7. Assess whether treatment recommendations are followed.
9. Measure the performance of providers at all levels (for example, individual physicians, medical groups, ACOs).
10. Collect performance measurement data efficiently.46

Also, some employers have engaged together in more active measurement of inpatient care through The Leapfrog Group. The Leapfrog Group launched in 2000 as a national voluntary program that engages employers in value-based health care purchasing. The Leapfrog Hospital Survey and related Hospital Safety Score, publicly released in 2012, include: (SCIP) measures, foreign object-retained and other outcomes, and patient safety indicators (for example, death among surgical inpatients, postoperative PE/DVT, and so on) from CMS Hospital Compare. The Hospital Safety Score methodology has been criticized as inaccurate, unreliable, and unfair by the American Hospital Association. (R. Umdenstock. Personal communication. June 22, 2013) Purchasers who have thus far been reluctant to use the Hospital Safety Scores by limiting consumer choices to higher-scoring hospitals may reconsider if more reliable surgical reporting is not available.43,47

The health insurance plans as well as purchasers have been actively involved in the regional data aggregation projects that started in the mid-2000s. The Robert Wood Johnson Foundation’s 14 Aligning Forces for Quality (AF4Q) regional collaboratives and the AHRQ’s 24 Chartered Value Exchanges have generally focused on preventive screening and management of diabetes and cardiovascular diseases. Partnerships across health insurance plans and purchasers with health care providers have been valuable to engage communities in performance measurement and reporting.48 This practice should be expanded into surgery and surgical outcomes.

2. Surgeons and surgical specialties need to continue to develop more robust data sources to supplement/aggregate with administrative and enrollment data to partner with health insurance plans in quality improvement. This may need to include clinical data as well as patient experience data.

3. Health insurance plans and purchasers need to continue to consider regional data aggregation partnerships and how to expand from preventive care and chronic disease management into surgical performance measurement.


13. Young, GJ. 2012. Multistakeholder regional collaboratives have been key drivers of public reporting, but now face challenges. *Health Affairs*. 31(3).


APPENDIX A: STATUTE OF LIMITATIONS

At a minimum, all public reports should clearly indicate the following in the information in their statute of limitations:

- Date of creation
- Date of the most recent update
- Date of expiration
- Dates for the data used in the report. For example, a report created in 2012 will likely be based on 2011 or 2010 data.
- Whether the report time frame is based on claims date or admission/discharge date or some other determinant for inclusion/exclusion
APPENDIX B: GLOSSARY AND DEFINITIONS

**Accountability**
The obligation to disclose periodically, in adequate detail and consistent form, to all directly and indirectly responsible or properly interested parties, the purposes, principles, procedures, relationships, results, incomes, and expenditures involved in any activity, enterprise, or assignment so that they can be evaluated by the interested parties. “Report cards” on managed care plan performance are an example of accountability in health care. Available at http://www.ahrq.gov/qual/hcqgloss.pdf. Accessed November 8, 2012.

**Appropriate Use Criteria (AUC)**
Appropriate Use Criteria specify when it is appropriate to use a procedure. An “appropriate” procedure is one for which the expected health benefits exceed the expected health risks by a wide margin. Often, sound data is not available or does not provide evidence that is detailed enough to apply to the full range of patients seen in everyday clinical practice. Nevertheless, physicians must make daily decisions about when to use or not use a particular procedure. AUCs facilitate these decisions by combining the best available scientific evidence with the collective judgment of physicians in order to determine the appropriateness of performing a procedure. Available at http://www.aaos.org/research/Appropriate_Use/auc_new.asp. Accessed November 19, 2012.

**Attribution**
A key issue for resource measurement for care provided by more than one provider, such as episodes of care, is how to attribute primary and contributory accountability for the resources used. Various algorithms, mainly based on visit counts and payment amounts, have been used. Different algorithms lead to different assignments, and every algorithm needs to be adjusted based on market characteristics, such as the availability of specialists and geographic or cultural isolation. No national consensus guidelines for provider attribution are available. Available at http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/perfmeasguide/perfmeaspt3.html. Accessed January 30, 2014.

**Clinical Outcome/Clinical Endpoint**

**Composite Measure**

**Donabedian Model of Patient Safety**
Donabedian’s structure–process–outcome model has long served as a unifying framework for examining health services quality and assessing patient outcomes. Donabedian defines structure as the physical and organizational properties of the settings in which care is provided, while process is the treatment or service being provided to the patient, and outcomes are the results of the treatment. From the standpoint of patient safety, Donabedian’s model provides a unified patient safety framework and permits an examination of how risks and hazards embedded within the structure of care have the potential to cause injury or harm to patients. For example, individual or team failures in a health care delivery setting are consistently identified as a leading cause of negative patient outcomes. This focus on the system of care is fundamental to improving quality.

**Efficiency Measures**
A subset of resource use measures that compare the production of products of a specified level of quality. Most resource use measures are not efficiency measures by this definition because they do not explicitly incorporate a measurement of the quality of the product. Available at http://www.ahrq.gov/qual/perfmeasguide/perfmeaspt3.htm. Accessed August 13, 2013.
Exclusion Criteria
The criteria, or standards, set out before a study or review. Exclusion criteria are used to determine whether a person should participate in a research study or whether an individual study should be excluded in a systematic review. Exclusion criteria may include age, previous treatments, and other medical conditions. Criteria help identify suitable participants. Available at http://effectivehealthcare.ahrq.gov/glossary-of-terms/?pageaction=showterm&termid=105. Accessed January 30, 2014.

Health Outcomes
The changes in current or future health status of individuals or groups of persons that are attributable to previously provided medical care. Health outcomes include mortality and morbidity (for example, following surgery), physical, mental and social functioning, costs of care, and quality of life. Available at http://www.ahrq.gov/qual/hcagloss.pdf. Accessed November 8, 2012.

Inclusion Criteria
The criteria, or standards, set out before a study or review. Inclusion criteria are used to determine whether a person can participate in a research study or whether an individual study can be included in a systematic review. Inclusion criteria may include gender, age, type of disease being treated, previous treatments, and other medical conditions. Inclusion criteria help identify suitable participants. Available at http://effectivehealthcare.ahrq.gov/glossary-of-terms/?filterletter=i. Accessed January 30, 2014.

Misclassification

Outcome Measure
A measure of what happens or does not happen after a process, service, or activity is performed or not performed. Outcome measures quantify an organization or provider’s results in providing services. Available at http://www.ahrq.gov/qual/hcagloss.pdf. Accessed November 8, 2012.

Process Measure (Process Indicator)

Process of Care

Public Reporting
Data, publicly available or available to a broad audience free of charge or at a nominal cost, about a health care structure, process or outcome at any provider level (individual clinician, group, organization). Available at http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0048354/. Accessed January 30, 2014.

Quality of Medical Care
The understanding of quality applied to health care; the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Available at http://www.ahrq.gov/qual/hcagloss.pdf. Accessed August 13, 2013.

Reliability
Reliability is an analysis of whether the variation seen in resource use is due to measurement error or to true differences in performance. The reliability of various resource use measures is largely unknown. Health plans currently use arbitrary cutoffs, such as 30 episodes per physician, and therefore are often unable to profile as many as one-third of the eligible physicians in their networks. Available at http://www.ahrq.gov/qual/perfmeasguide/perfmeaspt3.htm. Accessed August 13, 2013.
Resource Use Measures
Indicators of the cost and efficiency of health care provision. Health care resource use measures reflect the amount or cost of resources used to create a specific product of the health care system. The specific product could be a visit or procedure, all services related to a health condition, all services during a period of time, or a health outcome. Available at http://www.ahrq.gov/qual/perfmeasguide/perfmeaspt3.htm. Accessed August 13, 2013.

Risk Adjustment
In performance measurement, the use of severity of illness measures such as age to estimate the risk (the measurable or predictable chance of loss, injury, or death) to which a patient is subject before receiving a health care intervention. The purpose of risk adjustment is to ensure that comparisons of performance measures across organizations are fair and that observed differences are due to variation in provision of care rather than differences in patient populations served. Available at http://www.ahrq.gov/qual/hcqgloss.pdf. Accessed August 13, 2013.

Sensitivity
The ability of a test to identify correctly people with a condition. A test with high sensitivity will nearly always be positive for people who have the condition (the test has a low rate of false-negative results). Available at http://effectivehealthcare.ahrq.gov/index.cfm/glossary-of-terms/?filterletter=s. Accessed January 30, 2014.

Specificity
The ability of a test to identify correctly people without a condition. A test with high specificity will rarely be wrong about who does NOT have the condition (the test has a low rate of false-positive results). Available at http://effectivehealthcare.ahrq.gov/glossary-of-terms/?filterletter=s. Accessed August 13, 2013.

Surgical Care Improvement Project
The Surgical Care Improvement Project (SCIP) is a national quality partnership of organizations interested in improving surgical care by significantly reducing surgical complications. SCIP Partners include the Steering Committee of 10 national organizations who have pledged their commitment and full support for SCIP. Available at http://www.jointcommission.org/surgical_care_improvement_project/. Accessed August 13, 2013.

Validity
Whether a test or technique actually measures what it is intended to measure. Validity can refer to an individual measurement or to the design and approach taken in a clinical research study. Available at http://effectivehealthcare.ahrq.gov/index.cfm/glossary-of-terms/?filterletter=v. Accessed January 30, 2014.
APPENDIX C: SUMMARY

I. BASIC OPERATING TENETS OF PROVIDER PUBLIC REPORTING

1. All reports should make their methodology publicly available and should include a detailed description of any data used to estimate performance (i.e., the data source), use of statistical risk-adjustment techniques, the selection of performance measures, and how surgical performance was categorized. Reporting bodies should not use “black box” proprietary measures, which make it impossible to audit the report results.
2. Each report should be independently deemed reliable and valid prior to release.
3. Reports must be transparent about the observation period for a given quality measure, including the differentiation between long-term follow up and short-term outcomes.
4. Include a statute of limitations within the public report. Outdated reports must be removed from circulation.
5. Use proper risk adjustment, as determined by the appropriate specialty society, to ensure ongoing access for patients who are at higher risk of complications and poor outcomes.
6. Ensure that specialty societies have an opportunity to provide input regarding recommended physician measures chosen for public reporting and participate on the workgroup or panel selecting measures for the reports.
7. Standardize reporting format.
8. Provide opportunity for individual surgeon review and feedback before public reporting. Ensure a proper appeals process, including the process for managing contested reports.
9. Conduct pilot tests to determine usefulness and effectiveness of reports.
10. Evaluate the extent to which the report fulfills its stated purpose and identify any unintended consequences, with special focus on addressing misclassification.
11. Public reports should not be used to establish the standard of care or duty of care owed by a health care provider.

II. GENERAL ISSUES IN REPORTING

1. Clinical data generally provide more accurate and relevant information compared with claims data and should be used solely or in combination with claims data. Local, state, and federal government agencies as well as regional and national specialty societies that have supported registries that produced high-quality clinical data audited for completeness and accuracy and provided a basis for risk adjustment models that appropriately account for patient severity are well-suited to generate public reports.
2. Attribution must distinguish between the primary surgeon and other practitioners managing the various components of the surgical procedures and perioperative care.
3. Appropriateness criteria must be driven by evidence-based medicine or clinical guidelines with multi-stakeholder consensus, similar to the rigorous standards for quality measurement.
4. Public reports must accurately describe surgeons’ practice profiles.
5. Data in reports must be defined by and relevant to procedures being reported.

III. AUDIENCE-DEPENDENT ISSUES

A. PHYSICIAN AUDIENCE

1. Consider principles crucial for physician engagement.
2. Tailor a confidential performance feedback report specifically for the surgeon.
3. Report on the type of quality measures meaningful to physicians including Donabedian’s system approach (structure, process, and outcome) and AHRQ National Quality Measures Clearinghouse domains for clinical quality measures (process, access, outcomes, structure, patient experience), appropriateness of care/resource use, shared decision-making, care coordination, and continuity of care.
4. When choosing measures for physician public reporting or payment, consult evaluation criteria used by the leading major national organizations.
APPENDIX C: SUMMATION

B. PATIENT AUDIENCE
   1. Report on patient-focused measures, which are more likely to be understood by and credible with patients.
   2. Public reports for patients should focus on elective surgical procedures because the majority of patients in emergent care situations will not have the opportunity to review public reports on surgeons.
   3. Tailor a report specifically for the surgical patient.
   4. Customize reports based on procedures, conditions, and populations of interest to the patient.
   5. Reports should provide a framework to foster patient understanding.
   6. Make information available at the time when patients are most likely to use it.
   7. Establish credibility of reports from the patient perspective.

C. PAYER/PURCHASER AUDIENCE
   1. Consider the Consumer-Purchaser Disclosure Project’s 10 criteria for meaningful and usable measures of performance.
   2. Surgeons and surgical specialties need to continue to develop more robust data sources to supplement/aggregate with administrative and enrollment data to partner with health insurance plans in quality improvement. This may need to include clinical data as well as patient experience data.
   3. Health insurance plans and purchasers need to continue to consider regional data aggregation partnerships and how to expand from preventive care and chronic disease management into surgical performance measurement.
APPENDIX D: PRIVATE FEEDBACK REPORTING AUDIENCES, FUNCTIONS, AND INFORMATION FLOW
