



**Statement of the
American College of Surgeons**

Presented by

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To

Health Information Technology Policy Committee Meaningful Use Workgroup

RE: Hearing on needs of the specialist community, patients receiving care from specialists, as well as gathering information from those currently operating in an electronic environment

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Dr. Paul Tang, Dr. George Hripcsak, and distinguished members of the Health Information Technology Policy Committee Meaningful Use Workgroup (Workgroup), thank you for the opportunity to testify today on behalf of the 75,000 members of the American College of Surgeons (the College). My name is Don Detmer. I am the Medical Director for the Advocacy and Health Policy Division for the American College of Surgeons, and Professor Emeritus and Professor of Medical Education in the Department of Public Health Sciences at the University of Virginia and Visiting Professor at CHIME, University College of London. I am the founder and co-chair of the Blue Ridge Academic Health Group, current chair of the Institute of Medicine membership committee, chair of the board of MedBiquitous, associate editor of AMIA's Standards Standard, and a director of the Corporation for National Research Initiatives.

SPECIALTY PANEL QUESTIONS

We appreciate that the Workgroup is facilitating dialogue regarding the needs of the specialist community and information gathering in an electronic environment. There is concern among our members and the specialist community that Stage 2 and Stage 3 Meaningful Use (MU) objectives will continue to make it difficult for specialists to comply in adopting electronic systems.

The ACS supports the adoption of electronic health records (EHRs) and widespread information exchange to improve care; however, we feel there may well be need for greater flexibility to allow providers to successfully meet the criteria of meaningful use and implement electronic systems. Additionally, we feel that the high thresholds for the proposed stage 2 objectives are overly ambitious for some specialists given the current state of EHR products. Stated differently, before increasing thresholds for CPOE and similar objectives, we feel there must be adequate analysis showing that eligible professionals are successfully implementing and attaining stage 1 thresholds.

Since so many MU measures are primary care focused, the lack of exclusions creates a compliance problem for specialists. For example, eight of the 15 Stage 1 core measures and 3 of the 10 Stage 1 menu options do not include an exclusion category. Furthermore, many of the exclusions for measures under both the core and menu sets do not allow an exemption for specialists who do not routinely perform the activity described. We feel that specialists should not have to report on those measures that are not relevant to their scope of practice or services that they routinely provide to their patients, given the challenge of implementing EHRs into their practice environments. Much of the data identified are not routinely collected, measured, or managed by surgeons, or the details of the data are not directly relevant to surgery. Therefore, we stress the importance of including MU objectives that are relevant to specialists and appropriate for surgery. Refining the list of quality measures to include those that are specialty-focused will be a significant step toward improving care through implementation of EHRs and electronic information exchange.

As the creator of the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP), the ACS is well-positioned to provide input to the

Workgroup on performance measurement and feedback using electronic systems. Indeed, the ACS would be delighted to work directly with ONC and others to develop some appropriate MU objectives for the surgical community. The ACS NSQIP is the one of the only surgical multispecialty, prospective, risk-adjusted, audited, validated, outcomes-based surgical improvement program in the United States, and has been demonstrated repeatedly in peer reviewed settings to improve care, improve outcomes, decrease costs, and decrease variation. We address these issues in greater detail below in our responses to the questions relevant to the specialty panel.

PANEL 3: POPULATION DATA, INCLUDING REGISTRIES: HOW CAN EHRs FACILITATE SPECIALTY MANAGEMENT OF POPULATIONS, INCLUDING MEASURING AND FEEDING BACK PERFORMANCE?

EHRs can facilitate specialty management of populations, including measuring and feeding back performance data. To achieve these goals, we must all give greater attention to the relevant policy and research infrastructure needed to actualize the learning healthcare system that assures improvements over time. Registry data on surgical populations is a key component of achieving this goal.

Registries can serve as a deep reservoir for researchers interested in clinical trials and outcomes research and are a means to engage population data, much of which may not be available outside the context of a registry.

Today, we believe that registries already generate complex, useful data of sufficient quality that they can be used to track outcomes and to improve surgical patient care, giving healthcare providers a model for organizing and managing their networks to ensure multidisciplinary, integrated, and comprehensive services. The results should produce substantial cost savings across the nation largely through improved patient care. Currently, surgical data registries are an invaluable aid in this process because they provide a means to track and make such data available. Much of the data collection process engages paper processes and human reviewers but with greater focus and investment, substantial progress might be made to lessen this costly and time-consuming approach.

Going forward, in order to more efficiently measure and manage the quality of care for populations of surgical patients, EHRs should be capable of tracking relevant pre-, peri-, and post-operative data across care settings so as to allow surgeons to obtain data from and coordinate effectively with referring physicians and others as appropriate.

1. How do you currently assess your performance in caring for your patients and compare your performance to others?

Several national surgery-related registries exist, and we strongly believe that participation in such registries is an excellent method to assess and compare performance for improvement purposes to help hospitals and surgeons to know their own results and eventually to offer patient groups aggregate information with respect to quality. Safety

may represent a special circumstance in terms of reporting. Through the use of risk adjusted outcomes, providers are given the opportunity to benchmark their care. Examples of such registries include, but are not limited to the following:

- The ACS National Surgical Quality Improvement Program (ACS NSQIP) is the first nationally validated, risk-adjusted, multi-specialty, outcomes-based, systems focused program to measure and improve the quality of surgical care. Based upon evaluation data, we believe that as a clinically based program, ACS NSQIP detects and averts more complications than administrative QI programs, resulting in improved patient care and significant returns, financial and otherwise, on investment for participating hospitals. Certified surgical clinical reviewers collect, validate, and submit data, including preoperative risk factors, intraoperative variables, and 30-day postoperative mortality and morbidity outcomes for patients undergoing major surgical procedures in both the inpatient and outpatient setting. Data is presented to hospitals enrolled in the program via comprehensive semiannual reports and real-time, continuously updated, online benchmarking reports.
- The ACS National Cancer Data Base (NCDB) is a nationwide oncology outcomes database for more than 1,500 Commission on Cancer Accredited Programs in the United States and Puerto Rico. Data related to approximately 75 percent of all newly diagnosed cases of cancer in the United States are captured at the institutional level and reported to the NCDB. The data are used to explore trends in cancer care, create regional and state benchmarks, and serve as the basis for quality improvement. The ACS CoC is concluding the beta phase of a new initiative, the Rapid Quality Reporting System (RQRS). The RQRS uses evidenced-based consensus quality of cancer care measures endorsed by the National Quality Forum (NQF) to provide “real clinical time” feedback through a Web-based reporting system to participating facilities. Prospective alerts are also sent out to inform hospitals and their physicians of the need for anticipated evidence-based care for breast, colon, and rectal cases. Over 65 programs across the U.S. are testing this novel reporting system, and the ACS CoC seeks to roll out RQRS to the remaining programs by January 2011. This will enable ACS CoC accredited programs to prospectively monitor process of care with the anticipated result being the improvement of the coordination and delivery of evidence-based cancer care.
- The ACS National Trauma Data Bank (NTDB) is the largest aggregation of North American data relating to trauma patients. NTDB annual reports characterize trauma care in North America for both adults and children, and NTDB benchmark reports compare hospitals to similar institutions on patient demographics, raw mortality, injury type, injury severity, length of stay, and other pertinent measures. Trauma centers use the benchmark reports and the research dataset to create extensive comparisons to other centers and gauge their own performance.

- The ACS Trauma Quality Improvement Program (TQIP) provides risk-adjusted benchmarking of designated/verified Level I and II trauma centers to track outcomes and improve patient care. TQIP relies and builds upon the existing trauma infrastructure of data collection, reporting, and performance improvement through extensive trauma registrar training opportunities, rigorous data validation, and risk adjusted outcomes models. TQIP uses a systems approach to improving trauma care in participating centers.
- ACS Bariatric Surgery Database Approved centers of the ACS Bariatric Surgery Center Network Accreditation Program report bariatric surgical outcomes data to the ACS Bariatric Surgery Database. The data is complete, uniform, encrypted, and de-identified to protect the confidentiality of patients, surgical facilities, and surgeons. At present this approach has served the immediate needs for quality assurance. This longitudinal database requires a 100% capture of all cases. Participating Bariatric Centers have real-time access of their non-risk-adjusted outcomes data collection for benchmarking purposes.
- ACS Practice Based Learning System (Case Log) The ACS Practice Based Learning System (PBLs), also known as the Case Log, was developed in 2005 as a web-based secure way for Fellows of the ACS to contribute to quality/performance improvement, quality reporting, and maintenance of individual certification. The Case Log data registry collects about 30 data points, including patient demographics, diagnosis, co-morbid conditions, procedures, complications and outcomes. The database now contains over 1,000,000 patient records with almost 2,000 participants. From its start in 2005, the Case Log is now growing at a rate of almost 100% per year. Reports available to participants include procedure lists, information on outcomes, and benchmarking.
- The American Society of Plastic Surgeon's (ASPS) Tracking Operations & Outcomes for Plastic SurgeonsSM (TOPS)SM Program This ASPS registry was created in 2002. TOPS is a Web-based data collection process that captures plastic surgery procedures, clinical outcomes, and patient satisfaction results. TOPS is available to all ASPS members. TOPS is unique because it is physician focused, rather than facility focused. The TOPS registry stores cases a surgeon performs at each facility where he/she is on staff. Data entered through the Web-based TOPS interface are used by the surgeon in a variety of practice situations such as comparing cases and outcomes across facility type (inpatient, outpatient hospital, ambulatory surgical center, and office-based surgery facility) and to benchmark patient surgical outcomes, patient satisfaction results and practice patterns against their peers. ASPS uses the de-identified data for multiple purposes including compilation of the National Clearinghouse of Plastic Surgery Statistics and monitoring clinical outcomes and emerging trends.
- The Society of Thoracic Surgeons (STS) National Database This registry is the premier clinical data registry for cardiothoracic surgery. It includes three component parts: the Adult Cardiac Surgery Database, the General Thoracic

Surgery Database, and the Congenital Heart Surgery Database. More than 90 percent of all adult cardiac surgery centers nationwide participate in the Adult Cardiac Database and 70 percent of the congenital heart surgery programs participate in the STS Congenital Database. Surgeons add new patient data on a continuous basis thereby providing a highly dynamic, up-to-date picture of cardiothoracic surgical practice.

- Consumer Assessment of Healthcare Providers and Systems (CAHPS) Surgical Care Survey This survey was developed by the ACS and the Surgical Quality Alliance (SQA) to address the need to assess and improve the experiences of surgical patients. This questionnaire focuses on aspects of surgical quality that are important to patients and for which patients are the best source of information. Practices, health plans, and insurers can use the survey results for quality improvement initiatives and incentives. Specialty boards may use the survey for maintenance of certification. In time, the advent of widespread secure patient Web portals through MU may make these assessments less expensive and at the same time more robust.

2. What are the principal benefits (“value proposition”) of registry participation for physicians in your specialty?

Registry participation provides data related to performance to be measured and collected for feedback and improvement purposes. Data on an individual practitioner level is captured by certain data registries such as the STS data registry, TOPS and the ACS Practice Based Learning System (Case Log), data on a facility/system level is captured by other data registries such as the ACS NQSIP, and data on a patient experience of care is captured through tools such as the CAHPS Surgical Care survey.

The College has worked extensively to advance methods of risk adjustment and to combine data from multiple sources to develop meaningful measures of surgical care.

Working collaboratively with CMS, the ACS NSQIP staff has developed five surgery related, outcomes-based cross-cutting quality measures. They include:

1. A risk adjusted vascular surgery lower extremity bypass measure;
2. A risk and procedure mix adjusted surgical site infection (SSI) measure;
3. A risk and procedure mix adjusted urinary tract infection (UTI) measure;
4. A colon resection outcomes measure; and
5. A risk and procedure mix adjusted elderly surgery measure, which evaluates the outcomes of all procedures performed in a facility for persons 65 years and older.

Creating and administering the ACS NSQIP registry has allowed the ACS to develop surgical quality measures to improve care for the surgical patient. Additionally, participation in registries allows for benchmarking and comparative feedback on physician/team/hospital performance. In time, it is anticipated that specific computer-executable decision support systems within EHRs will couple relevant knowledge bases

with clinical decision-making which, when tied to outcomes data, should result in continuous quality improvement.

In addition to the ACS NSQIP, the ACS CoC has been actively engaged in the process of promulgating performance measures for breast and colorectal cancer. The ACS CoC developed, and is the steward of, six of the quality of cancer care measures for breast and colorectal disease endorsed by the National Quality Forum (NQF). Facilitated by the NQF, the ACS CoC, the American Society of Clinical Oncology (ASCO), and the National Comprehensive Cancer Network (NCCN) synchronized their developed measures to ensure that a unified set was put forth to the public. Four of the measures endorsed in 2007 by the NQF as evidence-based *accountability measures* have been reported back to ACS CoC accredited programs since 2005. These measures include:

1. Radiation therapy is administered within one year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer.
2. Combination chemotherapy is considered or administered within four months (120 days) of diagnosis for women under 70 with AJCC T1cN0M0, or Stage II or III hormone receptor negative breast cancer.
3. Tamoxifen *or* third generation aromatase inhibitor is considered or administered within one year (365 days) of diagnosis for women with AJCC T1cN0M0, or Stage II or III hormone receptor positive breast cancer.
4. Adjuvant chemotherapy is considered or administered within four months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer.

Two other measures are *quality improvement* measures and are intended to be used for internal monitoring of performance within each CoC accredited program. They include:

1. At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer.
2. Radiation therapy is considered or administered within six months (180 days) of diagnosis for patients under the age of 80 of with clinical or pathologic AJCC T4N0M0 or Stage III receiving surgical resection for rectal cancer.

ACS continues to develop, and reevaluate the soundness of evidence-based guidelines and performance measures in order to improve outcomes, effectiveness and efficiency.

As mentioned above, we do not currently have the needed policy infrastructure to assure access to large secure registries of individual longitudinal health record data. The problem was not important when the HIPAA legislation was passed in 1997 but this issue has become more critical to medical progress with each ensuing year. The Human Genome Program decoded the genome and followed that up with structural biology determining the structure of key proteins. In the last decade, the Clinical Translational Science Awards awarded by the National Institutes of Health across the nation have led to translational bioinformatics. This emerging scientific discipline alongside research informatics that gives us the opportunity to match, at the molecular level, genomic and

proteomic data with epigenetic information, e.g., data drawn from the health and disease histories of individuals and populations.

Kenneth Beutow made the declaration that we all succumb to what are essentially our own ‘orphan’ molecular diseases. This represents an historic shift in diagnosis and eventually treatment but it will require access to authenticated personal health information on large numbers of individuals and population. Only such access will assure substantial progress going forward. In the past, we classified illnesses by their target organ or system, e.g., liver or nervous system. Gaining secure access to much larger sets of person-specific health record information offers humanity the opportunity to make major advances in the diagnosis and treatment of human illness at both the individual and population levels. And, without access to such files in this nation, such progress will only be made by Americans and others doing this work in other nations who have sufficient interest in making such progress that they offer legitimate researchers these opportunities.

The passage of HIPAA and subsequent legislation and regulation has facilitated access to anonymized information while the passage of the Genetic Information Nondiscrimination Act of 2008 and the Affordable Care Act of 2010 have offered additional critical protections to such data. Further, there are now both protections and penalties at the national and state levels to diminish individual risk to acceptable levels to move forward. It is now time for the United States to offer Americans the opportunity to directly support this critical life-giving research at the national level as a matter of public policy.

To this end the ACS supports facilitating access to authenticated nonanonymized person-specific health data, in accordance with privacy and security protections, unless the patient wishes not to participate and withdraws access to their data from such use through widely publicized transparent processes. These processes would include totally transparent program management processes available for review on a Website that includes information relating to opting out without giving reasons for doing so, published audits of researchers who access the data, and prompt publication of audits that reveal any wrongful disclosures. Further, to assure validation of their data for research purposes, a unique identifier would be assigned to their data and used solely for personal authentication for research purposes. We feel this is a key mechanism to foster biomedical innovation in America while demonstrating to the public the value of health IT, and their own personal altruistic contribution as citizens to a more hopeful future for them and coming generations. We believe that confidential and secure access to longitudinal health data provides for numerous important purposes related to research and quality improvement. Other nations have dealt with this issue directly and are well ahead of us.

3. What are best practices for individual and aggregated data feedback to physicians and their teams?

Research has shown that feedback of data can change the clinical behavior of physicians and their teams, but the likelihood of success in this regard has been shown to depend

upon a number of criteria. First, the data must be considered clinically relevant in terms of content and local circumstances, the people doing the research must be considered credible, and the result needs to be fed back on a timely basis. If the feedback offers an opportunity for group discussion among the involved clinicians, or at least a respected credible group of local clinicians, there is greater likelihood of impact. And, where EHRs are available, if newer treatment algorithms can ease the future use of the revised treatment protocols, this too helps. Showing improved performance and outcomes as a result of making such changes further reinforces desired best practices.

Important items to be utilized include clinical data, risk-adjusted data, procedure mix-adjusted data, clinically relevant measures (face validity), appropriate statistical analysis, and appropriate attribution.

4. Where do you get the data needed for feedback?

Historically, data has come from two major approaches. Arguably, the most visible, least valid, and least successful have come from studies that use claims data based upon billings for services. ACS has made a demonstrated effort to glean specific information retrospectively from medical and related records. Clearly, we need to move to widespread automatic collection of relevant data based upon evidence-based, validated guidelines whether generated locally or nationally. This is an informatics challenge as much as a clinical challenge. The EHR's terminology and semantic meaning must be identical to written or spoken content, and EHR systems must have sufficient interoperability that findings can be aggregated in a valid manner.

From the registry perspective, it is imperative that the registries are rigorous in their data collection techniques, that the data are audited, that the data collectors are trained, and that there are strict definitions for the variables.

5. What are barriers to monitoring populations, and how do you overcome them?

There are significant barriers to monitoring populations. The way in which HIPAA discriminates between quality studies as a matter of business operations, as opposed to research, is a policy barrier to monitoring populations. Clinical researchers may not pursue relevant quality findings at the institutional level to determine if they represent more widespread issues offering safer or higher quality approaches for broader populations. At the 2011 Town Hall meeting discussing current and future clinical research policies at the AMIA Clinical Research Informatics Summit, clinical research informaticians had general agreement that this policy is problematic.

While barriers to collecting appropriate and adequate data do exist, there are some solutions. This can be overcome with a concerted effort to collect data for important and measurable items – most successfully led by people who are experienced in developing and running registries. It is important to note that a research registry is not the same as a quality improvement registry given researchers often explore and investigate with large-sized registries, while quality improvement registries tend to be as parsimonious as

possible- targeting quality issues directly. However, both can inform one another with the latter often helping with hypothesis generation. Being able to generate standardized patient profiles from EHR data including problem lists and procedures performed along the lines of MedBiquitous standards might help revolutionize credentialing and licensure, as well as quality and safety improvement. Achieving a 'data commons' presents substantial interoperability and cultural issues among those holding the repositories, in addition to dealing with concerns regarding security issues.

The low level of research funding for quality and safety with respect to informatics is another barrier. Added support for relevant research funded through the National Library of Medicine alone and also working in concert with the Agency for Healthcare Quality and Research could help address this issue.

Thank you, again, for the opportunity to provide testimony regarding the needs of the specialist community, patients receiving care from specialists, as well as gathering information from those currently operating in an electronic environment. If you have any questions about our testimony, please contact Bob Jasak in our Washington office. He can be reached at bjasak@facs.org or at (202) 672-1508.