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Improving Patient Outcomes in Gynecology: the role of large data registries and big data analytics

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Introduction: Quality and Value in Gynecology—delivering effective and efficient care

Gynecology is a truly unique surgical specialty in that it is one of a very few specialties that is responsible for the management, both non-surgical and surgical, of an entire organ system. While gynecologic procedures are extremely common, there is substantial variability in the practice of gynecology across the United States. This variability includes the geographic gynecologic surgical rate, administration of prophylactic antibiotics consistent with ACOG guidelines, and the offering of non-surgical treatment alternatives prior to surgery.(1-4) The performance of most gynecologic procedures is an elective preference-sensitive choice with most gynecologic procedures for benign indications having both non-surgical and surgical management options. Corona et al, demonstrated that many women (38%) are not offered alternative treatments prior to hysterectomy.(4) As recently suggested by Wright et al, focusing on the appropriateness of surgical indications and offering alternative treatments prior to surgery for benign gynecologic conditions should serve an important role in the future measurements of the quality care women receive in the United States.(8)

Over the past decade, there has been a groundswell movement in health care, across all medical specialties, to improve the quality, consistency and value of the care we provide to patients. The Center for Medicare and Medicaid Services (CMS) in conjunction with mandates from the Affordable Care Act (ACA), passed by Congress in 2010, has developed

several initiatives centered on the concept of paying for quality care. CMS is currently instituting payment penalties to hospitals for complications also known as hospital acquired conditions (HAC) such as catheter associated urinary tract infections (CAUTI), central line associated bloodstream infections (CLABSI), surgical site infections (SSI) and ventilator associated pneumonia (VAP). Through directed national efforts some early successes have been met, such as targeted goal reductions of 40% in HAC in some areas.

Another quality initiative from CMS is the Physician Quality Reporting System (PQRS).⁽⁹⁾ This system initially allowed eligible professionals (EPs), which includes physicians and other healthcare providers, to voluntarily report to CMS on attainment of approved quality measures within the scope of their clinic practice. As of 2015, there is now a payment penalty for Medicare reimbursements for EPs who do not participate in PQRS. The challenge facing gynecologists is to find 9 distinct and endorsed PQRS measures that apply to their scope of practice and the patient population that they serve. Reporting in the PQRS system presents substantial challenges to EPs. This has led to the institution of Qualified Clinical Data Registries (QCDR) approved by CMS as a vehicle to PQRS reporting. Participation in a CMS approved QCDR fulfills the PQRS reporting requirements to avoid payment penalties.

Quality Metrics: what should be measures? How should it be measured?

Value-based care is quality health care delivered effectively and efficiently. The success of value-based health care models is contingent on reducing over-use or waste. While many current efforts to improve quality are centered on reducing under-use (e.g. performing the appropriate screening tests as recommended, increasing appropriate vaccination rates), perhaps the best way to control health care spending to reduce over-use (e.g. unnecessary testing) in the U.S. health care system and focus on the elimination of low-value care.⁽¹⁰⁾ One promising strategy to reduce low-value care are the Choosing Wisely® campaign sponsored by the American Board of Internal Medicine. ⁽⁹⁾ The second main focus to reduce low-value care is the investment in accountable-care organizations (ACO) that contract to provide care for given populations, assuming risk in order to gain in shared savings resulting from the provision of high quality care.⁽¹¹⁻¹³⁾

The first step in determining the quality of care delivered in gynecology is creating meaningful ways to measure the care women receive. Using claims data (e.g. data based solely on billing) to determine quality care is limited and often inaccurate.⁽¹⁴⁾ Often claims data misclassifies events, fails to measure severity of complications, and does not provide enough information for adequate risk-adjustment. Data registries were created to collect accurate information on patients with enough clinical information to allow for adequate risk-adjustment of postoperative outcomes. It is hoped that feedback from clinical data registries with participating hospitals, group practices and individual surgeons will form the build blocks of quality improvement in gynecology.

Surgical Registries

Collecting accurate data on surgical outcomes from medical records and then applying meaningful risk-adjustment to compare surgical outcomes across surgeons and hospitals has

a proven track record of success in cardiothoracic and general surgery. The Society of Thoracic Surgeons (STS) national database and the American College of Surgeons national Quality Improvement Project (ACS NSQIP) are two successful examples of well-established surgical data registries. Both registries currently require significant institutional investment, not only to pay annual registry fees, but also to pay the salaries of trained research personnel to abstract data through a detailed chart review process. Information abstracted through chart review is then analyzed and risk-adjusted for patient complexity to provide meaningful feedback for hospitals, practices and surgeons. The benefits of collecting information through detailed chart review leads to more accurate data for risk-adjustment and better ascertainment of outcomes than billing data alone.(14)

Both STS and NSQIP registries advocate that two features—meaningful accurate risk-adjusted data and timely feedback—have led to the successful implementation of these registries. Participating sites receive feedback on their own outcomes every 3-6 months so that sites can direct quality improvement efforts to the areas that need most attention and initiate institutional or system-wide practices to evaluate and track the progress from process improvement. This feedback is much more timely and frequent than the PQRS system that reports quality metrics of EPs annually and with significant delay from when the service was provided.

Society of Thoracic Surgeons (STS) National Database

In 1989, the Society of Thoracic Surgeons (STS) developed a database to collect reliable outcomes data for cardiothoracic surgery to address flaws in the US Health Care Financing Administration's publically reported hospital mortality data following cardiac surgery based on billing data.(15) The three STS data registries have been widely successful with over 90% of adult cardiac surgery programs in the United States participating. Currently, STS sponsors three large registries: the STS-Adult cardiac surgery database, the STS-general thoracic database, and the STS-congenital heart surgery database. These databases collect high-quality point-of-care and chart-abstracted data that is audited to maintain excellent reliable, valid, and risk-adjusted data of its participants. As mentioned previously, current data captured from these registries requires significant investment in personnel devoted to chart-abstraction and data entry, and usually paid for by the hospital where the surgery is performed,.

The STS databases have been able to provide highly credible performance assessment with appropriate risk adjustment which has allowed for the creation of 31 STS-sponsored National Quality Forum (NQF)-endorsed performance measures, most of which are risk-adjusted outcomes measures. Two important features of the STS outcomes measures that contribute to the success of the registry are: 1) the measures are “risk-adjusted” and 2) the outcomes are reported at the group/hospital (not the individual provider) level. Risk adjustment helps to avoid unintended consequences of providers “cherry-picking” patients to avoid bad outcomes measurements and allows for better comparisons across different institutions. Secondly, reporting at the hospital level ensures that care of the patient is seen as a “team sport” since the care a patient receives during a hospital admission depends not just on surgical technical skills, but also on perfusionists, operating room staff,

anesthesiologists, postoperative nursing care, appropriate staffing, hospital care pathways, and other consulting physicians and providers. There is moderate evidence to support that measuring “networks” rather than individual surgeons can decrease unintended consequences of performance analysis.(16)

The American College of Surgeons National Surgical Quality Improvement Project (ACS NSQIP)

In 1986, Congress passed Public Law 99-166 mandating that the Veterans’ Affairs (VA) hospitals report their risk-adjusted surgical mortality and morbidity with the national average. To respond to this mandate, the VA founded the Surgical Risk Study of the 44 busiest VA surgical centers between 1991 and 1993.(17) This early work identified preoperative predictors of 30-day postoperative mortality and morbidity. The goal of the Surgical Risk Study which later became the VA National Surgical Quality Improvement Project (VA NSQIP) was to improve the quality of care by using risk-adjustment to compare outcomes. The hallmark of this risk-adjustment was based on Iezzoni’s “algebra of effectiveness”(18) that:

$$\text{Patient Factors} + \text{Effectiveness of Care} + \text{Random Variation} = \text{OUTCOME}$$

Analysis of data from the NSQIP registry resulted in development of risk calculator models used to predict, based on preoperative patient characteristics, the risks of postoperative complications.(19) The number of “observed” complications is then compared to the number of “expected” complications (termed Observed to Expected or O/E ratio). Low outliers are hospitals with O/E ratio of less than 1 and therefore are performing better than expected.

The VA NSQIP was a highly successful program and has resulted in a 47% reduction in postoperative mortality and a 43% reduction in composite postoperative morbidity.(20) In 1994, the program was expanded to include all VA hospitals. In 1998, the NSQIP program was trialed in 3 private sector hospitals and expanded to include 14 private hospitals in 2001. The program was so successful that in 2005 the American College of Surgeons (ACS) launched the ACS NSQIP which was available to any institution in the US. Currently, participating sites receive feedback on hospital and surgeon performance for 30-day postoperative outcomes from mortality to major complications to surgical site infections recognized after discharge. This feedback allows hospitals to determine whether they are performing optimally (better than expected) and what systematic issues need to be address to improve outcomes (e.g. changes in order sets for VTE prophylaxis, postoperative extubation, workflow, etc).

Currently over 450 US hospitals participate in ACS NSQIP. Hospital participation requires considerable institutional investment and full-time equivalents (FTEs), usually trained research nurses, to abstract the data from the medical record for participation. If a surgeon's hospital or institution does not current participate in the ACS NSQIP program, any member of the ACS can participate in the surgeon specific registry (SSR) to track individual outcomes. One way to fulfill CM Physician Quality Reporting System (PQRS) requirements

is to participate in a qualified registry and the ACS SSR allows surgeons to meet these requirements to avoid payment penalties. A gynecologist who is a member of ACS can elect to participate in the ACS SSR.

Two recent research articles have questioned the success of the NSQIP program in overall quality improvement.(21, 22) In one study, 44 hospitals participating in NSQIP were compared to 69 matched non-NSQIP hospitals via administrative data entered into the University HealthSystem Consortium database.(21) NSQIP hospitals were larger, had more annual inpatient discharges and had a higher Medicare case mix index indicating their patients were sicker. Complications, serious complications, and postoperative mortality were all reduced between 2009 and 2013. However, there was no statistically significant difference between the NSQIP hospitals and the non-NSQIP hospitals.(21) In a second study analyzing Medicare claims data, 263 ACS NSQIP hospitals were compared with 526 matched hospitals not participating in NSQIP.(22) Again, ACS NSQIP hospitals were larger, had more annual admissions, more operating rooms, and were more likely to be teaching institutions than non-NSQIP hospitals. Similarly, while postoperative mortality, serious complications, reoperations and readmissions were all reduced over first three years of participating in the NSQIP program, these improvements in outcomes were similar to hospitals not participating in NSQIP over the same three years.(22) While these reports are the first to question the value of NSQIP, they are limited in analyzing claims data. Rather than prompt feelings of futility in the importance of accurate and meaningful outcomes data, these reports should help shape future quality efforts to link *meaningful* surgical outcomes data to continued professional development, skill building and changes made within institutions.(23) herefore, the process of measurement alone is not enough; it is harnessing this information within individual institutions to enact meaningful change in quality that will drive improvement in patient outcomes.(23)

Data Registries in Gynecology

There are several examples of established data registries and newly-formed data registries that will be impacting and advancing the field of quality improvement in gynecology for years to come.

The SART registry

Perhaps the best example of a successful gynecologic registry is the Society for Assisted Reproductive Technology (SART) data registry established in 1996 that currently publically reports data on fertilization and live birth rates of over 90% of infertility clinics in the United States.(24) The information gained from the SART registry has resulted in numerous publications and guideline statements exponentially advancing the field of assisted reproduction with meaningful data.

FIBROID registry (25)

A second high successful registry in gynecology is the FIBRIOD registry. In response to a mandate from the Food and Drug Administration (FDA) to gather more information on the outcomes of uterine artery embolization (UAE), the Society of Interventional Radiology

founded the FIBROID registry in 1999.(26) Information gained from this highly successful effort to develop valid patient reported outcome tools and track outcomes after these procedures resulted in numerous publications and the establishment of clinical practice guidelines for UAE.(27)

COMPARE-UF (<http://compare-uf.org>), funded by the Patient-Centered Outcomes Research Institute (PCORI) in cooperation with the Agency for Healthcare Quality and Research, is the newest registry to compare different procedures used to treat uterine fibroids and their impact on women's reproductive life, ability to maintain future fertility and impact on menopause. COMPARE-UF is a network of sites caring for women with fibroids designed to address questions that are most important to women in order to improve patient care. The Data and Research Coordinating center is housed at Duke Clinical Research Institute (principal investigator, Dr. Evan Myers) and includes 10 other clinical centers throughout the United States. Patient centered outcomes including safety, efficacy and impact on overall health and quality of life will be tracked after women choose particular treatments with their own providers.

Pelvic Floor Disorders Registry (pfdregistry.augs.org)

In January 2012, the US FDA issued “522 orders” to 40 transvaginal mesh manufacturers to conduct post-market surveillance. In response, multiple private and public stakeholders collaborated to kick-start the Pelvic Floor Disorders Registry (PFDR). The PFDR was developed by representatives from the American Urogynecologic Society (AUGS) and its Registry Scientific Committee, the US Food and Drug Administration (FDA), the American Congress of Obstetricians and Gynecologists (ACOG), the Society for Urodynamics and Female Urology (SUFU), the American Urologic Association (AUA) and the Eunice Kennedy Shriver National Institutes of Child Health and Human Development (NICHD) as well as multiple industry representatives.

The PFDR is a prospective longitudinal database and participation is on a voluntary process. The PFDR registry serves two important roles. The first is fulfillment of FDA mandated trials on vaginal mesh products used for prolapse, and the second is for provider and site tracking of surgical outcomes, potentially for CMS PQRS mandate fulfillment and maintenance of certification. Currently, the PFDR includes industry-sponsored/522 order mandated surgical studies that started recruitment in 2014. Two additional volunteer treatment registries in the PFDR are expected to start enrollment in 2015. Surgeons may enroll patients in either a “Core Quality” or “Expanded” database. The core dataset involves minimal provider burden to assess effectiveness and safety outcomes, while the expanded dataset involves more composite outcome data to assess effectiveness, validated quality of life outcome data, and condition specific as well as electronic patient reported outcomes (ePRO). All healthcare providers involved in surgical or pessary management for pelvic organ prolapse can participate in the PFDR including gynecologists, urogynecologists, urologists, and other FPMRS specialists. Written informed consent is necessary for industry sponsored and expanded dataset studies but may be waived for the core dataset. The PFDR will allow for long-term comparative effectiveness and safety outcomes of surgical repairs using native

tissue, abdominally placed mesh, vaginally placed mesh, and non-surgical management (e.g pessary use).

Outcomes Database for Minimally-Invasive Gynecology-Surgical Review Corporation™

Members of AAGL's Centers of Excellence in Minimally-Invasive Gynecology (COEMIG) may participate in the outcomes database for minimally-invasive gynecology formed by AAGL and administered through the Surgical Review Corporation™. The Surgical Review Corporation has been highly successful in creating a data registry for outcomes in bariatric and metabolic surgery established in 2007.

Society of Gynecologic Oncologist Clinical Outcomes Registry

The Society of Gynecologic Oncologists has established a clinical outcomes registry for endometrial, ovarian and cervical cancer.(28) The Society of Gynecologic Oncologist Clinical Outcomes Registry (SGO COR) has enrolled over 1,500 patients and seeks to elucidate meaningful information into ways to improve the quality of care that women receive for gynecologic malignancies.

As these registries continue to grow and develop, the impact on our knowledge in gynecology will be profound. However, we are currently limited by the need for direct data entry. Meaningful use initiatives mandate massive national conversion to selected electronic medical record systems (EMRs) grounded in the hope that harnessing meaningful data from these EMRs will provide timely clinical decision support tools and answer clinically important research questions. With the implementation of EMRs throughout the country, vast amounts of data are entered electronically on a daily basis; however, our ability to retrieve data from these EMR systems for real-time clinical support decisions and for research has yet to be optimized.(29) The development of e-measures, electronic measures abstracted directly from a patient's clinical chart without the need for a paid chart abstractor, is an exciting and needed next step in the field of quality metrics. The challenge remains in building advanced and cost effective tools that can access data in a reliable way across multiple EMR systems.

Big Data: harnessing data into meaningful observations and improved workflow

Throughout the business world, very successful companies are analyzing vast amounts of data to better predict consumers' needs, even before consumers know what they need. "Big data" refers to the accumulation and analysis of large quantities of data and mining for repeating patterns that predict behaviors and outcomes.(29) Examples of companies using powerful analytics to successfully provide information about consumer habits include Google, Netflix, Amazon and Facebook.

In medicine, adoption of powerful analytics to improve healthcare quality has been slower than consumer behavior analysis. Potential applications of "big data" in medicine include diagnostic classification of disease and prediction of clinical courses for medically complex conditions.(30) The field of bioinformatics is entirely devoted to research conducted via

computer analysis and data science to answer critical questions about population health and behavior. The hope is to be able to develop real-time feedback and clinical support tools within the electronic medical record that helps providers deliver better care.

Conclusion

The ultimate goal of data registries and clinical support tools derived from big data is the ability to access accurate and meaningful data from an EMR in a reliable way without repetitive chart review or the need for direct data entry. Ultimately, the most efficient operating systems will include open-access computer codes that abstract data, in compliance with privacy regulations, from various EMRs in real-time to provide information about our patients, their outcomes and the quality of care that we deliver.

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