Registries

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tions, so it’s very important that we collect this type of data,” says PSF President-elect Kevin Chung, MD, “In the past, we have been satisfied with case series with a list of participating contributing data, but it did not represent a population perspective. Registries allow us to collect data on people with a common condition so that we can identify whether the disease is measured precisely, and determine appropriate predictors, and demographic and outcomes variables, to continue to assess whether the conditions for which we have data.”

The concept of medical registries, however, is not new – the American College of Surgeons established its National Surgical Quality Improvement Program (NSQIP) registry more than 20 years ago to measure and improve the quality of surgical care and reduce risk factors; more than 400 U.S. hospitals currently participate in the registry. The Society of Thoracic Surgeons established its Adult Cardiac Surgery Database in 1989; it currently holds more than 4.7 million records with 1,100 sites and 3,000 participating surgeons. The American College of Cardiology’s National Cardiovascular Data Registry launched in 1997 and has spawned six additional registries that have collected nearly 20 million records.

ASPS/PSF Registries

ASPS and The PSF have also long been committed to the development and expansion of medical registries. In 2006, The PSF launched the North American Breast Implant Registry (NABIR), which collected data on more than 51,000 procedures. Tracking Operations and Outcomes for Plastic Surgeons (TOPS) was developed in 2002 to collect data on plastic surgery procedures.

“There are a number of specialties that have some sort of registry platforms,” says ASPS President-elect Robert X. Murphy Jr., MD. “We’re not unique, but we are well-positioned because we did invest in TOPS early.” ASPS/PSF has also developed registries (see sidebars on pages 18-20) through The PSF’s Clinical Trials Network (CTN), which builds multi-center networks of leading clinicians and researchers to conduct clinical research in priority areas in plastic surgery. For example, in response to reports of a potential association between anaplastic large cell lymphoma (ALCL) and women with breast implants, the CTN developed the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE) registry led by Colleen McCarthy, MD, New York, to collect data on these rare cases, ASPS and The PSF entered

If there had been a registry in 2004, there wouldn’t be 400,000 women across the world walking around with PIP implants right now... Registries allow us to anticipate those problems many years before.

— Charles Verheyden, MD, PhD

The PSF president

The graphic above represents the PSF vision for a national, centralized data repository and data integration model for plastic surgery.

“The nice thing about registries is that you can do prospective analysis of things,” says Dr. Mehrara. “Most of the research conducted in the past has been retrospective analysis. The other words, you do 100 - 200 of the same procedure and then look back a year or two later, to see what your results were to calculate your complication rate and outcomes and things like that.”

“The problem with retrospective studies is that sometimes the data is entered incorrectly or it is not entered in the same exact way for each patient, so there may be inconsistencies,” he adds. “Therefore, retrospective studies tend to underestimate the complication rates or tend to be not as accurate as prospective studies. Registries are prospective, so we design the questions that we want to ask prospectively – and then design the questions that we want to be answered. This way everyone who enters into the registry enters their data in the exact same way, so we can fairly compare the data to us to really get the information, but also to be able to go through it.”

Building a National Breast Implant Registry

Another registry currently in development is the National Breast Implant Registry, a collaborative effort between ASPS/PSF, the FDA and breast implant manufacturers.

“The application of NABIR will allow us to collect population data so that when new technologies and new implant designs come to market, plastic surgeons will be able to assess them prospectively by carefully collecting the data points to ensure safety and good outcomes for patients,” says Dr. Verheyden. “And if there are ever any types of problems with new products, we’ll be able to pick it up much earlier.”

As the health care landscape evolves and evidence-based medicine continues to drive clinical decision-making in plastic surgery, Dr. Murphy says it will be critically important for ASPS members to have the ability to query large databases, in order to obtain information needed to answer difficult questions in the area of outcomes of care for quality improvement – and demonstrate they are providing a satisfactory level of patient care.

“Traditionally, clinical research has been based around comparing a modality or therapy against a placebo in the Affordable Care Act, the impetus has been to switch that paradigm to one which is comparative-effectiveness research – instead of against a placebo, you’re comparing one accepted therapy against another,” says Dr. Murphy. “The ultimate iteration of that is: What happens long-term, and are there rare-but-important events that occur as a result of this intervention or therapy at a time behind which normal data capture has happened?”

Future data collection models will include information that confirms process of care, continual quality improvement, patient safety, complications and the efficacy of plastic surgery procedures. Outcomes data is used to assess gaps in care (i.e., identify the types of complications that are most common for specific procedures), identify educational needs, determine the focus of clinical questions that need to be answered, and develop performance improvement measures. Some examples of this data include quality-of-life outcomes such as physical functioning and decreased pain.

Data provided on patient satisfaction will be important for advocacy efforts and to distinguish plastic surgery from other specialty groups.

Big data brings influence

As outcomes data are becoming essential measures of quality-health-care delivery, participation in registries between academic and centralized data collection has become a critical task for plastic surgery to proactively engage as a means of participating in the national quality and performance measurement agenda.

“From the perspective of our specialty, plastic surgeons traditionally have been operating in their own clinics and quite detached from the national conversation agenda,” adds Dr. Chung. “This can no longer be the case for our specialty if we want to be fully involved in the decision-making process when the evolving health care environment.”

For the many plastic surgeons in solo or small-group private practices who perform a significant volume of both elective cosmetic procedures as well as reconstructive work covered by third-party payers, contributing data to a registry can be burdensome.

“It is very high on The PSF’s agenda to markedly decrease the burden of collecting these data points through much more sophisticated and seamless collection systems,” says Dr. Chung. “In the past, collecting data from many different sites was difficult because we didn’t have the technology. Finding five to 10 minutes every day may be difficult for members given how busy we are, but we are exploring avenues and new technologies so that data can be integrated into a variety of electronic medical systems.”

As more plastic surgeons integrate EMR systems into their practices (and at the price to do so drops), contributing data is expected to become much easier.

“It’s been a huge challenge that plastic surgeons have been facing, but by virtue of what we do and being ‘small-shop’ types of players, we haven’t seen the need to invest,” adds Dr. Murphy. “That’s changing, and the demographic of our aver-