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 participants 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 quality is measured precisely, and determine appropriate predictors, and demographic and outcomes variables, to continue to assess whether the conditions for quality have been met."

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 of patient registries. In 2000, 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 platform," 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 sites to identify and 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 into a Cooperative Research and Development Agreement (CRADA) with the FDA to develop PROFILE, in which all past and future cases worldwide of breast implant-associated ALCL can be centralized to allow for enhanced surveillance and research.

Another project initiated through the CTN is the General Registry of Autologous Fat Transfer (GRAFT), which is being led by J. Peter Rubin, MD, Pittsburgh, and Babak Mehrara, MD, New York. Developed to determine the safety and efficacy of fat grafting to the breast, GRAFT is the first nationwide registry of fat grafting for aesthetic and reconstructive surgery in the United States.

"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 – in 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 all of 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 that it's much easier for us to not only 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 NBIR 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 and 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. With the advent of 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 beyond 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 within a guideline 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 registry development 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 policy discussion 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 within 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.

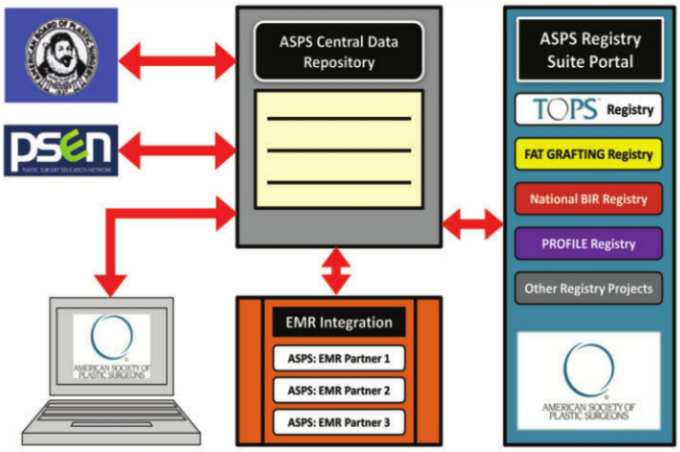
"It is very high on The PSF's agenda to markedly decrease the burden of collecting these data points through much more sophisticated and seamless collection systems," says Dr. Chung. "In the past, collecting data from our members was difficult because we didn't have the technology. Finding five to 10 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 as 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 late to adopt EMRs – 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-

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.

Seeking answers for ALCL in breast implant patients

The primary goal of the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE) registry is to better understand the role of breast implants in the etiology of ALCL in women with the device. While the PROFILE registry was in development, ASPS/PSF launched the *ALCL@plasticsurgery.org* e-mail address in September 2011 for plastic surgeons to report any cases of ALCL to the Society. Since the e-mail address was created, ASPS/PSF has been notified of more than 20 cases of the disease in women with breast implants. Data collection for this rare condition's surveillance registry started earlier this year and will include cross-referencing data with the FDA to ensure that there are no duplicate cases in the registry.

The resulting research will also focus on identifying potential risk factors and criteria for detection and management of the disease. The primary patient outcome being evaluated by this registry is the natural history of ALCL in women with breast implants, as well as the safety of the breast implants related to potential development of ALCL in determining whether an association exists between the disease and the device.

In addition to providing health care practitioners and patients with information they need about breast implants and treatment of ALCL, the confirmed cases in the PROFILE study will be available for analytical epidemiological studies.

The PSF serves as the coordinating center for the project and is responsible for all aspects of study coordination and project management. Data will come from a variety of locations and mediums, including medical centers, hospitals, private practice clinics and other entities. Participation in the registry is open to all patients worldwide who have had breast implants and a confirmed diagnosis of ALCL.

The PROFILE protocol received IRB approval in August 2012, with a waiver of patient consent. Potential and confirmed cases of ALCL can be reported to The PSF via e-mail at *ALCL@plasticsurgery.org*.